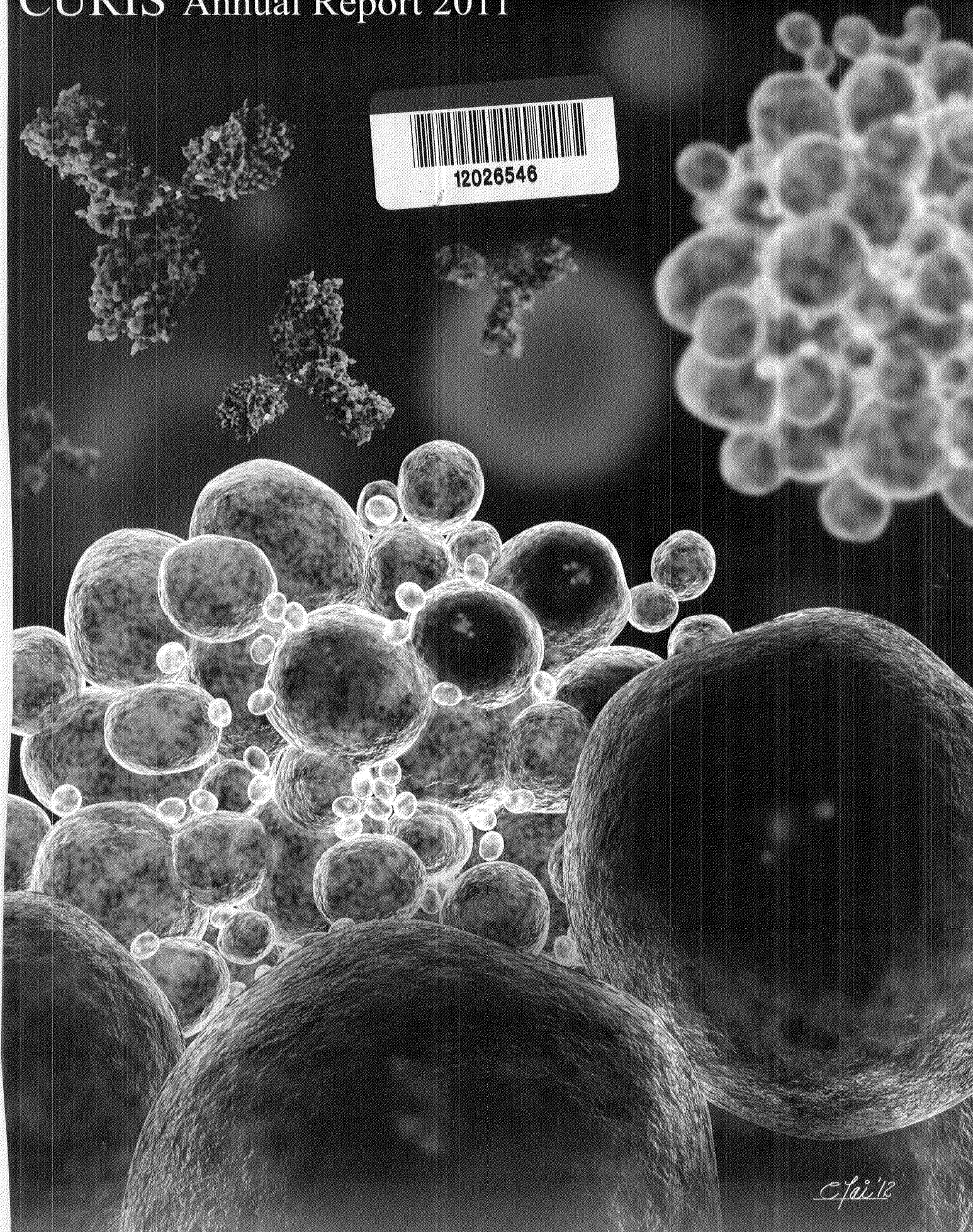


# CURIS Annual Report 2011



*E. J. 12*

Curis is a drug development company that is committed to leveraging its innovative signaling pathway drug technologies to seek to create new targeted small molecule drug candidates for cancer. Curis is building upon its previous experiences in targeting signaling pathways, including in the Hedgehog pathway, in its effort to develop proprietary targeted cancer programs.

Dear Stockholders,

The past year has marked a transformational period for Curis, and we and our partners have continued to make significant advances across all of our programs. Most notably, in January of this year, the FDA approved our collaborator Genentech's NDA submission of a first-in-class Hedgehog pathway inhibitor, Erivedge™, for the treatment of adults with advanced basal cell carcinoma, or BCC, that has spread to other parts of the body or that has come back after surgery, or a healthcare provider decides cannot be treated with surgery or radiation. Erivedge is the first and only FDA-approved medicine for patients with advanced BCC and is also the first and only Hedgehog pathway inhibitor to reach commercialization. Importantly, prior to the approval of Erivedge, no effective therapies were available for patients suffering with this debilitating and often life-threatening cancer. Erivedge is Curis' first involvement with a drug approval and represents a landmark event for the company, our stockholders and most importantly, for patients suffering from advanced BCC. Erivedge is also currently under regulatory review by the European Medicines Agency (EMA), which could increase patient access to Erivedge across Europe, if approved. Erivedge is also currently being studied in a Phase II trial of less severe forms of BCC and by third-party investigators in many other cancers.

In addition to the progress with Erivedge, our partner Debiopharm has made impressive steps forward with small molecule Hsp90 inhibitor Debio 0932. Debiopharm completed a Phase I dose escalation clinical trial in 2011 and initiated a Phase Ib expansion study in early 2012. In addition, Debiopharm expects to initiate a Phase I/II trial of Debio 0932 in non-small cell lung cancer patients in the first half of 2012 and present data from the Phase I dose escalation study at a medical conference in 2012.

Regarding our internal programs, in 2011 we completed a Phase I expansion study of our proprietary multi-target, cancer network inhibitor, CUDC-101, and also initiated a Phase I dose escalation study of this molecule in HPV negative (HPV-), locally advanced head and neck cancer patients in combination with standard of care radiation and cisplatin. We anticipate the initiation of a Phase I clinical trial of an oral formulation of CUDC-101 in the third quarter of 2012. Importantly, the oral formulation would allow us to expand into several indications beyond head and neck cancer due to dosing flexibility and convenience for patients. We also continued to make important progress in the development of our preclinical assets, evidenced by our selection of our next multi-target, cancer network inhibitor, CUDC-907, as a clinical drug candidate and our entry into a relationship with The Leukemia & Lymphoma Society (LLS), under which LLS will fund approximately 50% of our direct costs associated with the early clinical development of this molecule. We currently anticipate that we will file an Investigational New Drug application (IND) for CUDC-907 during the third quarter of 2012.

In addition to advancing our research and development programs, we have considerably strengthened our balance sheet and stand to significantly grow our revenues going forward. In 2011 and early 2012, we received approximately \$30 million in non-dilutive capital, primarily due to three milestone payments that we received from Genentech totaling \$24 million for the achievement of Erivedge regulatory objectives. We currently expect that our existing capital should provide us with adequate funding for our planned operations into early 2014. Importantly, this is before we start receiving royalty revenues from Genentech's U.S. sales of Erivedge, which we anticipate will begin in the second quarter of 2012. We also have the potential to receive royalties on sales of Erivedge in European territories beginning in 2013, provided that the EMA approves Erivedge, and are eligible to earn additional milestone payments in 2012 and 2013 from both Genentech and Debiopharm. Between our existing cash resources and the additional expected cash from royalty and milestone payments, we believe we have established a balanced business model ensuring that we are well-capitalized to advance our proprietary programs and create value for stockholders.

The following summarizes the status of our key programs.

### **Erivedge™**

Erivedge is a first-in-class Hedgehog pathway inhibitor that is being developed by Genentech and Roche under a 2003 collaboration between Curis and Genentech, a member of the Roche Group. BCC is the most common form of cancer in the United States and the most common type of skin cancer, accounting for over two million new cases annually. While the disease is generally considered curable when restricted to a small area of the skin, a small percentage of this population may have their cancer advance further into the skin, bones or other tissues, or spread to other parts of the body. In these cases, the disease is difficult to treat and often life-threatening.

Advanced BCC often results in severe deformity or impaired function of the affected organs, and patients historically have typically received one or more interventions, including surgery, radiation and various chemotherapies, none of which have proven effective for the treatment of advanced BCC. Erivedge is now the only approved drug for this advanced form of the disease.

The approval of Erivedge has material, immediate and long-term financial implications for Curis. Upon U.S. approval, Curis earned a \$10 million milestone payment from Genentech, and we expect Erivedge to provide Curis with significant potential future revenues from royalties on Genentech's net sales in the US market. Roche recently communicated that they estimate the market for advanced BCC in the U.S. alone to be approximately 14,000 patients, and they began sales in the first quarter of 2012 at a price of \$7,500 per month per patient. Genentech and Roche are working to closely identify the exact patient population as they launch this new drug.

In addition, we stand to receive potential additional milestone payments and royalties for development and regulatory approvals for Erivedge in advanced BCC in territories outside the US market. Erivedge is currently under review for approval by the EMA, and Roche has indicated that it currently anticipates possible approval in either late 2012 or early 2013.

Genentech is also conducting a separate Phase II clinical trial of Erivedge in patients with operable nodular BCC, which is a less severe form of the disease and accounts for a significant percentage of the over two million BCCs diagnosed annually in the United States. Genentech has advised us that further study and analysis of Erivedge in operable BCC is ongoing, including completing patient enrollment and treatment of patients. We currently anticipate that the study will be completed during early 2013.

In addition to the operable BCC study being conducted by Genentech, multiple trials in other cancers are ongoing by third-party investigators, including exploring Erivedge in additional BCC studies including in the pre-surgical treatment of BCCs, basal cell nevus syndrome (Gorlin syndrome), medulloblastoma, multiple myeloma, sarcomas and glioblastoma multiforme, as well as in pancreatic, small cell lung, gastroesophageal junction, gastric, breast, and prostate cancers, among others. We expect that some of these studies should yield data in 2012 and we look forward to additional potential data from these ongoing clinical studies and to providing further updates in the future.

#### **DEBIO 0932**

Debio 0932 is our synthetic, non-geldanamycin, orally available small molecule Hsp90 inhibitor, which we licensed to Debiopharm in August 2009. Debiopharm made significant progress with this molecule in 2011, completing the dose escalation portion of an ongoing Phase I clinical trial of Debio 0932 in patients suffering from advanced solid tumors. The clinical results observed in this study include single agent activity in certain cancers and what appears to be a highly favorable safety profile. Debiopharm has indicated that it expects to present results of this Phase I study at a medical conference during the first half of 2012.

Debiopharm also recently initiated a Phase Ib study of Debio 0932 and we expect that a Phase I/II study of Debio 0932 in non-small cell lung cancer patients will be initiated in the second quarter of this year. The objective of the Phase Ib study, an expansion cohort of certain solid tumor patients, will be to further assess the safety profile, pharmacokinetics and pharmacodynamics of Debio 0932 at a potential Phase II dose level, and to make a preliminary assessment of anti-tumor activity in patients with advanced solid tumors.

Our relationship with Debiopharm has provided Curis with important non-dilutive capital at a volatile time in the capital markets. We have received \$13 million under this agreement to-date and are eligible for our next milestone under the agreement, assuming that Debiopharm treats its fifth patient in a Phase II clinical trial. We currently anticipate that Phase II testing could initiate in the first half of 2013. We continue to be highly impressed with Debiopharm's professionalism in its efforts to date.

#### **CUDC-101**

CUDC-101 is our first-in-class EGFR, Her2 and HDAC inhibitor that has been designed with the goal of disrupting cancer "networks" and combating drug resistance mechanisms by concurrently inhibiting multiple



validated cancer targets with one drug. CUDC-101 is being developed to simultaneously inhibit both EGFR and Her2 at the cell surface signaling receptor level while also blocking intracellular histone deacetylase, or HDAC, epigenetic activity. We believe that this novel combination of targets enables a synergistic attack on multiple nodes, or points of intervention, in the overall pathway network used by tumors to survive, grow and invade surrounding tissue. Furthermore, we believe that this approach may provide more effective and more durable suppression of tumor biology by preventing or reducing access to drug resistance mechanisms and by attacking cancer cells at multiple points of intervention.

Our 2011 development of CUDC-101 was highlighted by our initiation of a Phase I study in HPV- locally advanced head and neck cancer patients in combination with the current standard of care therapies of cisplatin and radiation therapy. We are exploring head and neck cancer as the primary commercial disease setting for the current intravenous formulation of CUDC-101, as the drug targets the primary driving mechanisms of HPV- head and neck cancers, synergy has been reported with HDAC inhibition and radiation, our preclinical data have shown that CUDC-101 synergizes with cisplatin, and the IV dosing schedule aligns well with current standard of care, where patients must present to the clinic every weekday for 7 weeks. We are also continuing to progress an oral formulation of CUDC-101 and currently expect that we will file an IND during the third quarter of 2012.

### **CUDC-907**

Activation of the PI3K signaling pathway is believed to play a crucial role in cancer development and progression. As a result, the inhibition of this pathway is currently being investigated extensively as a potential cancer therapy. However, primary or acquired resistance appears to present a major challenge to the success of single-target molecules that are designed to inhibit the PI3K pathway due to the existence of redundant and compensatory pathways in cancer cells. We believe that CUDC-907's synergistic inhibition of HDAC and PI3K may enhance anti-tumor activity and overcome these limitations through durable blockade of cancer networks as opposed to single target inhibition.

We believe that we have received important external validation for this molecule when we entered into an agreement with LLS in late 2011, under which they will support our ongoing development of CUDC-907 for patients with B-cell lymphoma and multiple myeloma, funding approximately 50% of the development of CUDC-907, up to \$4 million. This agreement was entered into as part of LLS's Therapy Acceleration Program, a strategic initiative to speed the development of therapies that have the potential to change the standard of care for patients with blood cancers, especially in areas of high unmet medical need. We are currently conducting preclinical studies of CUDC-907 which are required to file an IND. We expect to file the IND in the third quarter of 2012 and then will start patient enrollment in a Phase Ia dose escalation clinical trial in patients with B-cell lymphoma and multiple myeloma. If this study is successful, LLS has also agreed to support our subsequent Phase Ib or Phase IIa study in one or more specific indications as well as our ongoing investigation of biomarkers for CUDC-907 in these diseases.

\*\* \*\* \*

We continue to evolve as a balanced and diverse biotechnology company focused on the goal of creating and maintaining significant value for our stockholders. We have achieved a great deal of progress during the past year and look forward to the prospects of continued progress and value creation in the pivotal years ahead, as we continue to pursue the advancement of our proprietary and partnered drug candidates.

As always, we thank our stockholders for their continued support, our Board of Directors and our advisory boards for their expert guidance and all of the Curis employees for their continued loyalty, hard work and dedication.

Sincerely,



Daniel R. Passeri  
President and Chief Executive Officer  
Curis, Inc.

# FORM-I OK

Curis 2011

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-K**

(Mark one)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2011

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number 000-30347

**CURIS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

**DELAWARE**  
(State or other jurisdiction of  
incorporation or organization)

04-3505116  
(I.R.S. Employer  
Identification No.) **Washington DC  
405**

4 Maguire Road  
Lexington, Massachusetts 02421  
(Address of principal executive offices) (Zip Code)

617-503-6500  
(Registrant's telephone number, including area code)

**Securities registered pursuant to Section 12(b) of the Act:**

Title of Each Class Common Stock, \$0.01 par value per share	Name of Each Exchange on Which Registered The NASDAQ Stock Market
---	--

**Securities registered pursuant to Section 12(g) of the Act:**

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ☒ Yes ☐ No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting company ☐

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) based on the last reported sale price of the common stock on June 30, 2011 was approximately \$188,823,000.

As of February 24, 2012, there were 77,512,426 shares of the registrant's common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Specified portions of the registrant's proxy statement for the annual meeting of stockholders scheduled to be held on May 30, 2012, which are to be filed with the Commission not later than 120 days after the close of the Registrant's fiscal year ended December 31, 2011 pursuant to Regulation 14A, have been incorporated by reference in Item 5 of Part II and Items 10-14 of Part III of this Annual Report on Form 10-K.

**CURIS, INC.**  
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## PART I

*This annual report on Form 10-K contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause Curis' financial, operating and business results to differ materially from those expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including without limitation any expectations of revenue, expenses, earnings or losses from operations, or other financial results; statements with respect to the plans, strategies and objectives of management for future operations; statements concerning product research, development and commercialization plans, timelines and anticipated results; statements of expectation or belief; and statements of assumptions underlying any of the foregoing. The risks, uncertainties and assumptions referred to above include risks that are described in "Item 1A-Risk Factors" and elsewhere in this annual report and that are otherwise described from time to time in our Securities and Exchange Commission reports filed after this report.*

*The forward-looking statements included in this annual report represent our estimates as of the filing date of this annual report. We specifically disclaim any obligation to update these forward-looking statements in the future. These forward-looking statements should not be relied upon as representing our estimates or views as of any date subsequent to the date of this annual report.*

### ITEM 1. BUSINESS

#### Overview

We are a drug discovery and development company that is committed to leveraging our innovative signaling pathway drug technologies in seeking to develop next generation network-targeted cancer therapies. We are building upon our experience in modulating signaling pathways, including the Hedgehog signaling pathway, in our effort to develop network-targeted cancer therapies. We conduct our research and development programs both internally and through strategic collaborations.

#### ***Hedgehog Pathway Inhibitor Program (Erivedge™)***

*Erivedge™ (vismodegib) capsule.* Our most advanced program is our Hedgehog pathway inhibitor program under collaboration with Genentech, Inc., a member of the Roche Group. The lead drug candidate being developed under this program is Erivedge, a first-in-class orally-administered small molecule Hedgehog pathway inhibitor, which is also referred to as vismodegib, GDC-0449 and RG3616. Erivedge is designed to selectively inhibit signaling in the Hedgehog pathway by targeting a protein called Smoothened. The Hedgehog signaling pathway plays an important role in regulating proper growth and development in the early stages of life and becomes less active in adults. However, mutations in the pathway that reactivate Hedgehog signaling are seen in certain cancers, including basal cell carcinoma, or BCC. Abnormal signaling in the Hedgehog pathway is implicated in over 90% of BCC cases.

In January 2012, Erivedge was approved by the U.S. Food and Drug Administration, or FDA, as the first and only FDA-approved medicine for adults with advanced forms of basal cell carcinoma that has spread to other parts of the body or that has come back after surgery or that their healthcare provider decides cannot be treated with surgery or radiation. It is not known if Erivedge is safe and effective in children. We earned a \$10,000,000 milestone payment from Genentech as a result of the FDA's approval of Erivedge in this indication and we are also entitled to receive royalties on future sales of the product. During the fourth quarter of 2011, we received a total of \$14,000,000 in milestone payments from Genentech relating to the FDA's acceptance of Genentech's New Drug Application, or NDA, for Erivedge and the European Medicines Agency's, or EMA's, acceptance for review of a Marketing Authorization Application, or MAA, for Erivedge that was submitted by Roche in December 2011. The Genentech NDA and Roche MAA applications were based on positive clinical data from ERIVANCE BCC/SHH4476g, a pivotal phase II study of Erivedge in patients with advanced BCC. We will receive an additional milestone payment if Erivedge also receives EMA marketing authorization, as well as royalties on any future sales in this territory.

Genentech is also conducting a separate phase II clinical trial of Erivedge in patients with operable nodular basal cell carcinoma, which is a less severe form of the disease and accounts for a significant percentage of the approximately two million BCCs diagnosed annually in the United States. We anticipate that the study will be completed during early 2013.

In addition to the BCC clinical trials being conducted directly by Genentech and Roche, Erivedge is also currently being tested in other cancers in trials under collaborative agreements between Genentech and either third-party investigators or the U.S. National Cancer Institute, or NCI, including treatment of BCC patients with basal cell nevus syndrome (Gorlin syndrome), medulloblastoma, sarcoma and glioblastoma multiforme, as well as in pancreatic, small cell lung, gastroesophageal junction, gastric, breast, and prostate cancers, among others.

### ***Network-Targeted Cancer Programs***

Our internal drug development efforts are focused on our network-targeted cancer programs, in which we are seeking to design single novel small molecule drug candidates that inhibit multiple signaling pathways that are believed to play roles in cancer cell proliferation. We refer to this approach as cancer network disruption. We believe that our approach of targeting multiple nodes in cancer signaling pathway networks may provide a better therapeutic effect than many of the cancer drugs currently marketed or in development since our drug candidates are being designed to disrupt multiple targets in the cancer network environment as compared to many other cancer drugs which are designed to disrupt only one target.

**CUDC-101.** Our lead candidate from these programs is CUDC-101, a first-in-class small molecule compound designed to simultaneously target histone deacetylase, or HDAC, epidermal growth factor receptor, or EGFR, and human epidermal growth factor receptor 2, or HER2, all of which are validated cancer targets. A significant amount of our capital resources are focused on the ongoing clinical development of this molecule. To date, we have completed a phase I dose escalation clinical trial of CUDC-101 in 25 patients with advanced, refractory solid tumors and a phase I expansion trial to test CUDC-101 in 46 patients with specific tumor types, including breast, gastric, head and neck, liver and non-small cell lung cancers. The phase I expansion trial was designed as an open-label study in which patients were treated with CUDC-101 at the maximum tolerated dose, which was determined in the phase I dose escalation study to be 275 milligrams per meter<sup>2</sup>. The primary objectives of this study were to compare the safety and tolerability of CUDC-101 in subjects with these specific advanced solid tumors when the drug is administered via one-hour intravenous infusion either on a five days per week schedule (one week on/one week off) or on a three days per week schedule (three weeks on/one week off).

During the third quarter of 2011, we treated the first patient in a phase I clinical trial of CUDC-101 in locally advanced head and neck cancer patients whose cancer is human papilloma virus, or HPV, negative. We have treated four patients in this trial as of February 24, 2012. The primary objective of this study is to evaluate the safety and tolerability of CUDC-101 when administered in combination with the current standard-of-care of cisplatin, a chemotherapeutic drug, and radiation. Upon determination of the maximum tolerated dose and assuming the otherwise successful completion of the phase I trial, we intend to conduct a randomized phase II two-arm clinical trial in which head and neck cancer patients will receive cisplatin and radiation plus or minus CUDC-101. The phase II study would seek to evaluate whether the addition of CUDC-101 can improve the efficacy of cisplatin and radiation therapy in this patient population. We currently estimate that we will initiate the phase II study in the first half of 2013.

We are also working on an oral formulation of CUDC-101, which we believe has the potential to make CUDC-101 more competitive in certain cancers such as non-small cell lung cancer or in other cancers where there are competing investigational or commercially available molecules that are orally administered. Pending the successful completion of ongoing formulation and preclinical development work, we intend to begin a phase I study of an oral formulation of CUDC-101 in the second half of 2012.

**CUDC-907.** In January 2011, we selected development candidate CUDC-907, an orally bioavailable, network-targeted small molecule that is designed to inhibit HDAC and phosphatidylinositol-3-kinase, or PI3K.

Our scientists are developing CUDC-907 based on published and internally generated data demonstrating that HDAC and PI3K inhibitors have synergistic interaction in certain preclinical cancer models. We believe that this synergistic mechanism of cancer signaling network disruption, which demonstrated efficacy and a favorable safety profile in a number of preclinical xenograft models, could translate into clinical advantages over single agents.

In November 2011, we entered into an agreement under which The Leukemia & Lymphoma Society, or LLS, will provide a portion of the funding of the development of CUDC-907 if we succeed in advancing this development candidate into a clinical trial for patients with B-cell lymphoma and multiple myeloma. Pending the successful completion of ongoing formulation and preclinical development work, we expect to file an investigational new drug application, or IND, with the FDA to test an oral formulation of CUDC-907 during the second half of 2012.

In addition to our development-stage programs, we continue to progress additional proprietary preclinical research programs and expect that we will select additional small molecule inhibitors from our preclinical portfolio in the future.

### ***Hsp90 Program***

*Debio 0932.* Our heat shock protein 90, or Hsp90, program is being developed by Debiopharm, a Swiss pharmaceutical development company, under an August 2009 license agreement between Curis and Debiopharm. The lead molecule under this license collaboration was designated Debio 0932 by Debiopharm. In April 2010, Debiopharm treated the first patient in a phase I clinical trial to evaluate the safety of Debio 0932 in patients suffering from advanced solid tumors. In 2011, Debiopharm successfully advanced Debio 0932 through the dose escalation portion of the phase I study. Debio 0932 was generally well tolerated, with no evidence of ocular or liver toxicity, both of which had been observed in previous clinical testing of certain other Hsp90 inhibitors. Debio 0932 also showed promising signs of efficacy in patients with advanced solid tumors in this study. Debiopharm has indicated that it expects to present phase I data from this phase I study at a medical conference during the first half of 2012.

Debiopharm advanced Debio 0932 into the phase Ib expansion portion of the study in the beginning of 2012. Debiopharm expects to treat approximately 30 patients in this phase Ib study, with the primary objectives of further assessing the safety profile, pharmacokinetics and pharmacodynamics of Debio 0932 at the recommended dose level of 1000mg daily that was established in the dose escalation portion of the Phase I clinical trial, and making a preliminary assessment of anti-tumor activity in patients with advanced solid tumors, including patients with non-small cell lung cancer.

Debiopharm has also indicated that it expects to initiate a combination Phase I/II study in non-small cell lung cancer patients in the second quarter of 2012. We are eligible for our next milestone payment under our license agreement if and when Debiopharm treats its fifth patient in a phase II clinical trial, assuming that Debiopharm advances Debio 0932 into phase II clinical testing. We currently anticipate that phase II testing could commence in the first half of 2013.

### **Product Development Programs**

We are developing drug candidates designed to treat cancer. Our product development initiatives, described in the chart below, are being pursued using our internal resources or through our collaborations with Genentech and Debiopharm. We believe that our collaborators provide significant additional resources and clinical development expertise to our programs. In addition, under these collaborations our collaborators have agreed to pay us contingent cash payments, assuming the achievement of development and regulatory objectives, and royalties on future product sales, if any.

Our research and development programs, both internal and under collaboration, are summarized in the following table:

<b>Product Candidate</b>	<b>Primary Disease</b>	<b>Collaborator/ Licensee</b>	<b>Status</b>
<b><i>Hedgehog Pathway Inhibitor</i></b>			
- Erivedge (vismodegib)	Advanced BCC	Genentech	FDA approval
- Erivedge (vismodegib)	Advanced BCC	Genentech	MAA review
- Erivedge (vismodegib)	Operable Nodular BCC	Genentech	Phase II
<b><i>Network-targeted Cancer Programs</i></b>			
- CUDC-101 intravenous formulation (HDAC, EGFR, Her2 inhibitor)	Cancer	Internal development	Phase I expansion
- CUDC-101 intravenous formulation (HDAC, EGFR, Her2 inhibitor)	Locally advanced HPV- head and neck cancer	Internal development	Phase I
- CUDC-101 oral formulation (HDAC, EGFR, Her2 inhibitor)	Cancer	Internal development	Development candidate
- CUDC-907 (HDAC, PI3K inhibitor)	Cancer	Internal development	Development candidate
- Other network-targeted cancer programs	Cancer	Internal development	Preclinical
- Debio 0932 (Hsp90 inhibitor)	Cancer	Debiopharm	Phase Ib

In the chart above, “FDA approval” means that Genentech’s NDA was approved by the FDA for commercialization of Erivedge in the United States. “MAA review” means that Roche has filed an MAA with the EMA, and the EMA has accepted and is currently reviewing the application for potential approval to commercialize Erivedge in Europe. “Phase II” means that Genentech is currently treating human patients in a phase II clinical trial, the primary objective of which is a therapeutic response in the patient population. “Phase I expansion” means that we are currently treating human patients with specific tumor types in an extension of our phase I dose escalation trial, at the maximum tolerated dose from such trial, the principal purpose of which is to evaluate the safety and tolerability of the compound being tested. “Phase Ib” means that Debiopharm is further assessing the safety profile, pharmacokinetics and pharmacodynamics of Debio 0932 at the recommended Phase II dose level, and seeking to make a preliminary assessment of anti-tumor activity in patients with advanced solid tumors. “Phase I” means that we are currently treating human patients in separate phase I clinical trials for CUDC-101, the principal purpose of which is to evaluate the safety and tolerability of the compound being tested. “Development candidate” means that we have selected a single lead candidate for potential future clinical development and are seeking to complete the relevant safety, toxicology, and other studies required to submit an IND application with the FDA seeking to commence a phase I clinical trial based on our testing in several preclinical models of human disease of various compounds from a particular compound class. “Preclinical” means that we are seeking to obtain evidence of therapeutic efficacy and safety in preclinical models of human disease of one or more compounds within a particular class of drug candidates.

Since our inception in 2000, substantially all of our revenues have been derived from collaborations and other agreements with third parties. For the year ended December 31, 2011, Genentech accounted for \$14,388,000, or 97%, of our revenue. For the year ended December 31, 2010, Debiopharm and settlement proceeds received from a former collaborator, Micromet, accounted for substantially all of our revenue, as



follows: Debiopharm, \$11,333,000, or 71%, and Micromet, \$4,000,000, or 25%. For the year ended December 31, 2009, Genentech and Debiopharm accounted for substantially all of our revenue, as follows: Genentech, \$6,229,000, or 73%, and Debiopharm, \$2,199,000, or 26%.

### **Hedgehog Pathway Inhibitor Program (Erivedge)**

The Hedgehog pathway is normally active during embryonic development and regulates tissue and organ formation by directly promoting cell division in specific cell types, and by activating other secondary signaling pathways that control the synthesis of growth factors and angiogenic (blood vessel-forming) factors. Malignant activation of the Hedgehog pathway is believed to play a central role in allowing the proliferation and survival of cancer cells, including basal cell carcinoma and medulloblastoma as well as colorectal, ovarian, pancreatic, small cell lung and breast cancers, among others.

Our Hedgehog pathway inhibitor technologies represent our most advanced program and are being developed in various cancer indications under a June 2003 collaboration agreement with Genentech. The lead drug candidate being developed under this program is Erivedge (vismodegib) capsule, a first-in-class orally-administered small molecule Hedgehog pathway inhibitor that is the first and only FDA-approved medicine for adults with advanced forms of basal cell carcinoma that has spread to other parts of the body or that has come back after surgery or that their healthcare provider decides cannot be treated with surgery or radiation. It is not known if Erivedge is safe and effective in children. Genentech and Roche are responsible for the clinical development and commercialization of Erivedge and are currently conducting a phase II clinical trial of GDC-0449 in operable BCC that was initiated in October 2010. In addition, Erivedge is also currently being tested in other cancers in trials under collaborative agreements between Genentech and either third-party investigators or the U.S. National Cancer Institute, or NCI, including in medulloblastoma, sarcoma and glioblastoma multiforme, as well as in pancreatic, small cell lung, gastroesophageal junction, gastric, breast, and prostate cancers, among others. Genentech completed two phase II clinical trials of Erivedge in 2010, including in advanced ovarian cancer and metastatic colorectal cancer. Neither of these studies met their primary endpoints of demonstrating a clinically meaningful extension of progression-free survival and Genentech has determined that it will not pursue further development of Erivedge in these two indications.

*Advanced Basal Cell Carcinoma.* In January 2012, Erivedge was approved by the FDA as the first and only FDA-approved medicine for adults with advanced forms of basal cell carcinoma. We earned a \$10,000,000 milestone payment from Genentech as a result of the FDA's approval of Erivedge in this indication and we are also entitled to receive royalties on future sales of the product. During the fourth quarter of 2011, we received a total of \$14,000,000 in milestone payments from Genentech relating to the FDA's acceptance of Genentech's New Drug Application, or NDA, for Erivedge and the European Medicines Agency's, or EMA's, acceptance for review of a Marketing Authorization Application, or MAA for Erivedge, that was submitted by Roche in December 2011. The Genentech NDA and Roche MAA applications were based on positive clinical data from ERIVANCE BCC/SHH4476g, a pivotal phase II study of Erivedge in patients with advanced BCC. We will receive an additional milestone payment if Erivedge also receives EMA marketing authorization, as well as royalties on any future sales in this territory.

In June 2011, Genentech reported positive data from ERIVANCE BCC/SHH4476g. ERIVANCE BCC/SHH4476g is an international, single-arm, multi-center, two-cohort, open-label phase II study that enrolled 104 patients with advanced BCC, including metastatic (33) and locally advanced BCC (71). Locally advanced BCC patients include patients whose lesions were inappropriate for surgery (inoperable, or for whom surgery would result in substantial deformity) and for which radiotherapy was unsuccessful or contraindicated. Metastatic BCC was defined as BCC that had spread to other parts of the body, including the lymph nodes, lung, bones and/or internal organs. The study was conducted at 31 sites in the United States, Australia and Europe. Study participants received 150 mg Erivedge orally, once daily until disease progression or intolerable toxicity. Tumor responses for metastatic BCC were measured by RECIST criteria. For locally advanced BCC, a novel composite endpoint was designed, which included reduction of size of lesions of at least 30% in longest dimension and/or complete resolution of locally advanced BCC ulceration.

The study met its primary endpoint showing that Erivedge substantially shrank tumors or healed visible lesions, with observed response rates of 43% of patients in the locally advanced BCC cohort and 30% of patients in the metastatic BCC cohort as assessed by an independent review facility. The median duration of response by independent review was 7.6 months for both metastatic and locally advanced BCC patients. The median duration on treatment was 10 and 9.7 months for metastatic BCC and locally advanced BCC patients, respectively.

The most common adverse events observed in the study (observed in greater than 10% of patients) were muscle spasms, alopecia (hair loss), dysgeusia (altered taste sensation), weight loss, fatigue, nausea, diarrhea, decreased appetite, constipation, arthralgias (joint pain), vomiting, and ageusia (loss of taste). In addition, a total of 3 of 10 pre-menopausal women developed amenorrhea, which is the absence of a period, while receiving Erivedge. Treatment emergent grade 3 laboratory abnormalities included hyponatremia (low sodium) in 6 patients, hypokalemia (low potassium) in 2 patients and azotemia (elevation of blood urea nitrogen) in 3 patients. Previous animal studies have indicated that Erivedge is embryotoxic and teratogenic. The FDA-approved labeling thus carries a boxed warning stating that Erivedge can cause fetal harm when administered to pregnant women based on its mechanism of action and recommends the use of contraception during and after treatment.

*Operable Basal Cell Carcinoma.* In October 2010, Genentech initiated a phase II clinical trial of Erivedge as a single-agent therapy for patients with operable BCC in which Genentech expects to evaluate Erivedge in approximately 50 patients with operable nodular BCC in a US-based, open label, two-cohort clinical trial. All patients will receive a 150 mg daily oral dose of Erivedge for 12 weeks. The primary outcome measure for the first cohort is the rate of complete histological clearance of target nodular BCC lesions at the time of tumor excision, which may occur up to 12 weeks following initiation of treatment, while the primary outcome measure for the second cohort is the rate of durable complete clearance of target nodular BCC lesions at the time of excision, which may occur up to 36 weeks following initiation of treatment.

Genentech has completed enrollment and data evaluation for patients treated in the first cohort of this study, and has submitted data from this cohort for presentation at a medical conference during the first half of 2012. Genentech has informed us that further study and analysis of Erivedge in operable BCC is required to determine a potential future development plan, including completing ongoing patient enrollment and treatment in the second cohort. We currently anticipate that the study will be completed during early 2013.

*Other Erivedge Clinical Trials.* In addition to the ongoing clinical trials that Genentech and Roche are conducting, Genentech and the NCI entered into a collaborative relationship that allows the NCI to study Erivedge in additional potential cancer indications. Third party investigators are conducting several additional clinical trials with Erivedge under this collaboration, including in medulloblastoma, sarcoma and glioblastoma multiforme as well as in pancreatic, small cell lung, gastroesophageal junction/gastric, breast, and prostate cancers, among others. Furthermore, an investigator-sponsored study evaluating Erivedge in patients with basal cell nevus (Gorlin) syndrome has been initiated.

Interim data from an investigator-sponsored study in basal cell nevus syndrome, or BCNS, was presented in April 2011 at the American Association for Cancer Research 2011 annual meeting. This phase II double blind, randomized placebo-controlled, two arm multicenter clinical study of Erivedge enrolled 41 BCNS patients from September 2009 to January 2011. This study is designed to assess the safety and efficacy of a 150 mg dose of daily oral Erivedge versus a placebo. A Data Safety Monitoring Board, or DSMB, tasked with reviewing the unblinded results from an interim analysis of 29 patients who completed an average of six months of drug treatment, subsequently recommended to end the placebo arm of the trial due to statistically significant differences between the two groups, in order for all of the patients enrolled in the trial to receive Erivedge treatment. The DSMB's analysis revealed that Erivedge reduced the rate of new BCCs from an average of 1.74 BCCs per month in the placebo group to 0.07 in the Erivedge group ( $p < 0.0001$ ). Erivedge also reduced the size of existing BCCs (-24 cm vs. 3 cm placebo, cumulative diameter,  $p = 0.006$ ). Observations related to Erivedge's safety were similar to what has been reported in previous clinical studies, including grade 1-2 taste loss, muscle cramps, hair loss and weight loss when compared to placebo were common. There were two grade 3-4 adverse events observed, including one grade 3 muscle cramp and one grade 4 depression. Overall, 28% of patients taking Erivedge discontinued participation due to adverse events.

Under the terms of our June 2003 collaborative research, development and license agreement with Genentech, we granted Genentech an exclusive, global, royalty-bearing license, with the right to sublicense, to make, use, sell and import small molecule and antibody Hedgehog pathway inhibitors for human therapeutic applications, including cancer therapy. We were responsible for performing certain funded preclinical research activities through December 2006. In November 2008, Genentech granted a sublicense to Roche for non-U.S. rights to Erivedge. Roche received this sublicense pursuant to an agreement between Genentech and Roche under which Genentech granted Roche an option to obtain a license to commercialize certain Genentech products in non-U.S. markets. In February 2010, we announced that Chugai Pharmaceutical Co., Ltd. had exercised its right of first refusal for the development and commercialization in Japan of Erivedge under an existing agreement with Roche.

Genentech and Roche have primary responsibility for worldwide clinical development, regulatory affairs, manufacturing and supply, formulation and sales and marketing. We are eligible to receive up to \$115,000,000 in contingent cash payments for the development of Erivedge or another small molecule, assuming the successful achievement by Genentech and Roche of specified clinical development and regulatory objectives. We have received \$42,000,000 of this amount including the \$10,000,000 payment that we earned in January 2012. We are also eligible to receive royalties on sales of any Hedgehog pathway inhibitor products that are successfully commercialized by Genentech and Roche. For Erivedge, we are entitled to a mid-to-high single digit royalty, which escalates within this range with increasing product sales. In certain specified circumstances, the royalty rate applicable to Erivedge may be decreased to a low-to-mid single digit royalty.

Unless terminated earlier, the agreement will expire six months after the later of the expiration of Genentech's obligation to pay royalties to us under the agreement or such time as no activities have occurred under the agreement for a period of twelve months. The agreement may be terminated earlier by either party for cause upon sixty days prior written notice. In addition, Genentech may terminate the agreement, either in whole or in part, without cause, upon six months prior written notice. In the event of any termination where specific license grants survive, we will continue to have the right to receive clinical development and regulatory approval milestones and royalties on product sales for such licensed compound, if any. If we terminate the agreement for cause or Genentech terminates the agreement without cause, all licenses granted to Genentech automatically terminate and revert to us. In addition, Genentech has agreed that it will no longer conduct any development or commercialization activities on any compounds identified during the course of the agreement for so long as such compounds continue to be covered by valid patent claims.

As a result of our licensing agreements with various universities, we are obligated to make payments to these university licensors totaling 5% of certain milestone and any royalty payments we receive from Genentech. From the inception of our Genentech collaboration through December 31, 2011, we have incurred expenses of \$1,600,000 related to such payments. We incurred expenses of \$500,000 upon receipt of the \$10,000,000 payment from Genentech for FDA approval of Erivedge that occurred in January 2012, and we will also be obligated to pay a total of 5% of any royalties we receive upon the sale of Erivedge to these sublicensees.

### **Our Proprietary Network-Targeted Cancer Programs**

Over the past several years, targeted cancer drugs have been considered by scientists and clinicians to be among the most promising cancer treatments for obtaining a therapeutic effect with less toxicity when compared with traditional chemotherapy, which, in addition to attacking cancerous cells, also tends to attack a broad range of healthy cells. A large body of published data shows cancers to have multiple, intersecting signaling pathways, or networks, that support survival, growth, and invasion. Targeting only one or two of these pathways has generally only led to modest improvements to existing standards-of-care and most cancer patients with solid tumors do not respond in a clinically meaningful manner. We believe that targeting the correct combination of critical signaling pathways within the network of cancer cell signaling pathways could provide a major improvement in outcomes for cancer patients.

We are utilizing our medicinal chemistry and biological expertise to develop a series of proprietary network-targeted cancer drug programs. In these programs we are focusing on the development of proprietary, small molecule single-agent drug candidates that target one or more molecular components within the network of signaling pathways associated with certain cancers. Each proprietary compound is being designed to inhibit one or more validated cancer targets, including, among others, EGFR, Her2, Bcr-Abl tyrosine kinase and phosphatidylinositol-3-kinase, or PI3k, in combination with inhibition of HDAC, which is a validated non-kinase cancer target. We are also seeking to develop proprietary, differentiated, single-agent, single-target drug candidates for cancer indications, as exemplified by Debio 0932. This molecule was discovered by us and licensed in 2009 to Debiopharm for further development.

HDAC inhibition is a core component in a majority of our network-targeted inhibitors. We believe that HDAC is a very promising non-kinase target for cancer therapy, particularly when combined with simultaneous inhibition of certain other targets. There is substantial preclinical evidence of synergistic induction of cancer cell death when HDAC inhibitors are combined with a diverse range of other targeted therapies or standard chemotherapeutic agents, demonstrating that HDAC inhibition may be more broadly effective in the treatment of cancer when integrated with other inhibitory activities. Currently, there are two FDA-approved HDAC inhibitors and several other HDAC-targeted drug candidates in clinical trials for cancer, many in combination with other agents or modalities.

We have filed a number of patent applications including a broad omnibus patent application that covers the drug design concept that is the basis for our network-targeted cancer programs, as well as numerous species filings relating to specific classes of compounds which we believe will constitute novel compositions from a patentability standpoint. We expect that we will continue to file additional patent applications covering new compositions in the future.

*CUDC-101.* CUDC-101 is the first compound we have selected as a drug candidate from our portfolio of network-targeted cancer programs. CUDC-101 is designed as a first-in-class single-agent therapeutic to simultaneously inhibit HDAC, EGFR and Her2. In preclinical studies, CUDC-101 demonstrated the potential to inhibit all three molecular targets resulting in the potent killing of a wide range of cancer cell lines that are representative of a variety of human cancer types, many of which have demonstrated resistance to various approved targeted agents.

Our data suggest that CUDC-101's mechanism of action involves the increased sensitization of cancer cells to EGFR and Her2 inhibition through HDAC inhibition. CUDC-101 simultaneously inhibits both EGFR and Her2 at the receptor level while blocking downstream HDAC inhibition within the cancer cells. Despite the existence of other molecules that seek to inhibit multiple targets, CUDC-101 is unique in its choice of targets which we believe enables a synergistic attack on multiple nodes or points in the overall pathway network that are used by tumors to survive, grow, and invade surrounding tissue. Utilizing the same targeted strategy with other currently available drugs would require combining two or three separate agents, which typically have mismatched dosing schedules and may display additive dose limiting toxicities. In contrast, we believe that CUDC-101, as a single small molecule, has the potential to act in the same cancer cells at the same time with fewer toxic side effects and thus potentially represents an important advance in targeted agent cancer therapy.

In April 2010, we completed a dose escalation phase I clinical trial of this molecule. This phase I trial was designed as an open-label, dose escalation study of CUDC-101 in patients with advanced, refractory solid tumors in which the primary objectives were to evaluate the safety and tolerability of escalating doses of CUDC-101 and to establish the maximum tolerated dose and dose limiting toxicities. Secondary objectives included the assessment of efficacy. The study was conducted at two clinical sites within the United States and enrolled 25 patients across several dose-escalating cohorts. CUDC-101 demonstrated promising evidence of antitumor activity in this study at doses ranging from 150 milligrams per meter<sup>2</sup> to 275 milligrams per meter<sup>2</sup>, including one confirmed partial response that was achieved in a gastric cancer patient at 275 milligrams per meter<sup>2</sup> and a stable disease of greater than three months observed in a refractory breast cancer patient at 150 milligrams per meter<sup>2</sup>. Two head and neck cancer patients, including one patient with salivary gland adenocarcinoma and one



patient with squamous cell carcinoma of the tongue, exhibited anti-tumor activity with a decrease of greater than 20% in their respective target lesions. We concluded dosing in this phase I dose escalation study in March 2010 and determined that 275 milligrams per meter<sup>2</sup> represented the maximum tolerated dose of CUDC-101. CUDC-101 also exhibited dose-proportionate increases in pharmacological parameters and what we believe to be a favorable safety profile. The most frequent adverse events were mild to moderate and included fatigue, vomiting, dyspnea (shortness of breath), pyrexia (fever), and dry skin.

In October 2011, we completed a phase Ib expansion trial to test CUDC-101 in 46 patients with specific tumor types, including breast, gastric, head and neck, liver and non-small cell lung cancers. The phase Ib expansion trial was designed as an open-label study in which these patients were treated with CUDC-101 at the maximum tolerated dose of 275 milligrams per meter<sup>2</sup> at seven study centers in the United States. The primary objectives of this study are to compare the safety and tolerability of CUDC-101 in subjects with specific advanced solid tumors when the drug is administered either on a five days per week schedule (one week on/one week off) or on a three days per week schedule (three weeks on/one week off). The secondary study objectives include evaluation of the pharmacokinetics and pharmacodynamic biomarkers following CUDC-101 administration and to assess the efficacy of CUDC-101 in this patient population. The safety profile observed to-date for both dosing schedules appears to be consistent with that observed in the phase I dose escalation study. In addition, we have observed stable disease in several patients in this study. Most notably, we have observed stable disease lasting more than 14 weeks in four patients: two patients with liver cancer and one patient each with head and neck and gastric cancer.

We presented the phase I dose escalation study data at the 22nd EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, and anticipate that we will present data from the phase I expansion study at a medical conference during the first half of 2012.

During the third quarter of 2011, we treated the first patient in a phase I clinical trial of CUDC-101 in locally advanced head and neck cancer patients whose cancer is human papilloma virus, or HPV, negative. The primary objectives of this study are to evaluate the safety and tolerability of CUDC-101 when administered in combination with the current standard-of-care of cisplatin, a chemotherapeutic drug, and radiation. Upon determination of the maximum tolerated dose and assuming the otherwise successful completion of the phase I trial, we intend to conduct a randomized phase II two-arm clinical trial in which head and neck cancer patients will receive cisplatin and radiation plus or minus CUDC-101. The phase II study would seek to evaluate whether the addition of CUDC-101 can improve the efficacy and durability of cisplatin and radiation therapy in this patient population.

We selected head and neck cancer as our first indication for potential phase II testing of CUDC-101 for several reasons. First, CUDC-101 demonstrated biological activity in two patients with head and neck cancer in the phase I dose escalation study, including a mixed response in a head and neck cancer patient at 150 mg/m<sup>2</sup> dose level and a tumor reduction of over 20% after just four weeks of study drug administration in a separate head and neck cancer patient at the 275 mg/m<sup>2</sup> dosing level. Second, our research team generated strong *in vitro* and *in vivo* preclinical data in head and neck cancer, exemplified by data in seven head and neck cancer cell lines that includes some of the highest potency observed of the cell lines in which CUDC-101 was tested. Lastly, we believe that this internal data is supported by published literature demonstrating that both EGFR and Her2 are often implicated in head and neck cancers.

There are approximately 30,000 newly diagnosed advanced head and neck cancer patients in the U.S. annually, of which approximately 60-70% have tumors that are HPV negative. It has been shown that head and neck tumors overexpress EGFR in 80-100% of cases, and also overexpress Her2 in 20-40% of cases. CUDC-101 is designed to inhibit both EGFR and Her2, potentially providing an added benefit for patients. CUDC-101 is also designed to target HDAC, which has been demonstrated to provide synergistic effects when combined with radiation therapy. We believe that CUDC-101's current intravenous formulation is suitable for this patient population because patients are required to receive daily radiation treatment for several weeks at their respective clinical centers.

We are also working on an oral formulation of CUDC-101, which we believe has the potential to make CUDC-101 more competitive in certain cancers such as non-small cell lung cancer where patients are generally on therapy for several months and there are competing commercially available molecules that are orally administered. Pending the successful completion of ongoing formulation and preclinical development work, we intend to begin a phase I study of an oral formulation of CUDC-101 during 2012.

*CUDC-907.* In January 2011, we selected development candidate CUDC-907, an orally bioavailable, network-targeted small molecule that is designed to inhibit HDAC and phosphatidylinositol-3-kinase, or PI3K.

Our scientists developed CUDC-907 based on published and internally generated data demonstrating that HDAC and PI3K inhibitors have synergistic interaction against cancer cells. In vitro mechanism of action studies demonstrate that CUDC-907 is able to inhibit Class I PI3Ks and upregulate molecules involved in cancer cell death. CUDC-907 has also demonstrated the ability to suppress multiple nodes of other survival pathways as a result of the epigenetic modification resulting from the inhibition of its non-kinase HDAC target. By contrast, we believe that the single-target PI3K inhibitors currently in clinical development only target the primary PI3K survival pathway and have been reported to have only limited effects on tumors with dysregulation of other signaling pathways.

CUDC-907 displays high exposure and long half-life in tumor tissue after IV administration and is orally bioavailable in animals. CUDC-907 exhibits anti-proliferation activity against a broad range of cancer cell types in *in vitro* studies, including cell lines that exhibit reduced sensitivity to single-target PI3K inhibitors. CUDC-907's anti-proliferation activity has been demonstrated to be up to 100-fold more potent than that of two leading PI3K inhibitors in development. CUDC-907 also inhibits tumor growth in preclinical xenograft models of hematology cancers and solid tumors with K-RAS mutations that exhibit reduced sensitivity to PI3K inhibitors, indicating that this compound may have broader activity than other leading PI3K inhibitors currently in clinical development. This compound also displays a favorable safety profile in our early safety evaluation. We believe that its synergistic mechanism of cancer signaling network disruption, efficacy in a number of preclinical xenograft models and favorable safety profile could provide rationale for further clinical development.

In November 2011, we entered into an agreement under which The Leukemia & Lymphoma Society, or LLS, will provide a portion of the funding for our ongoing development of CUDC-907 for patients with B-cell lymphoma and multiple myeloma if we succeed in advancing CUDC-907 into a clinical trial. We are currently conducting preclinical studies of CUDC-907 which are required to file an IND. We expect to file the IND and then will start patient enrollment in a phase Ia dose escalation clinical trial in the second half of 2012 in patients with B-cell lymphoma and multiple myeloma.

*Other Network-Targeted Cancer Programs.* In addition to our development-stage programs, we continue to progress additional proprietary research programs and expect that we will select additional small molecule inhibitors from our preclinical portfolio in the future.

*Debio 0932.* Heat shock protein 90, or Hsp90, is a member of a class of proteins called molecular chaperones that play a fundamental role in the folding, stabilization and degradation of other cellular proteins, or clients, under normal or stressful conditions. Hsp90, in particular, has become an attractive therapeutic target for the treatment of cancer because a majority of its client proteins are involved in cellular signaling transduction and have been identified as potential contributors to various aspects of cancer cell growth and survival. Inhibitors of Hsp90 activity may be of therapeutic value if they can prevent Hsp90 proteins from protecting the particular client proteins involved in cancer and allow them to be degraded, thereby inducing cancer cell death. In our preclinical studies, our lead candidate Debio 0932 demonstrated potent efficacy across a broad range of cancers in preclinical cancer models and exhibited promising pharmacological features in preclinical testing, particularly its high oral bioavailability, high tumor penetration and extended tumor retention. Tumor regression was also observed after treatment of Debio 0932 in mouse xenograft models of acute myelogenous leukemia, breast, non-small cell lung, gastric and colon cancers as well as in glioblastoma brain cancers. In our preclinical testing, the compound also demonstrated an ability to effectively cross the blood brain barrier and extend survival in preclinical intracranial glioblastoma and brain metastasis models.

In August 2009, we granted a worldwide, exclusive royalty-bearing license to develop, manufacture, market and sell our Hsp90 inhibitor technology, including our preclinical development candidate, Debio 0932, to Debiopharm. Debiopharm has assumed all future development responsibility for Debio 0932 and Debiopharm or a Debiopharm licensee will incur all future costs related to the development, registration and commercialization of products under the agreement.

In April 2010, Debiopharm treated the first patient in a phase I clinical trial to evaluate the safety of Debio 0932 in patients suffering from advanced solid tumors. In 2011, Debiopharm successfully advanced Debio 0932 through the dose escalation portion of the phase I study. Debio 0932 was generally well tolerated, with no evidence of ocular or liver toxicity, both of which had been observed in previous clinical testing of certain other Hsp90 inhibitors. Debio 0932 also showed promising signs of efficacy in patients with advanced solid tumors in this study. Debiopharm has indicated that it expects to present phase I data from this phase I study at a medical conference during the first half of 2012.

Debiopharm advanced Debio 0932 into the phase Ib expansion portion of the study in the beginning of 2012. Debiopharm expects to treat approximately 30 patients in this phase Ib study, with the primary objectives of further assessing the safety profile, pharmacokinetics and pharmacodynamics of Debio 0932 at the recommended dose level of 1000mg daily that was established in the dose escalation portion of the Phase I clinical trial, and making a preliminary assessment of anti-tumor activity in patients with advanced solid tumors, including patients with non-small cell lung cancer.

Debiopharm has also indicated that it expects to initiate a combination Phase I/II study in non-small cell lung cancer patients in the second quarter of 2012. We are eligible for our next milestone payment under our license agreement if and when Debiopharm treats its fifth patient in a phase II clinical trial, assuming that Debiopharm advances Debio 0932 into phase II clinical testing. We currently anticipate that phase II testing could commence in the first half of 2013.

Debiopharm paid us an up-front license fee of \$2,000,000 pursuant to the agreement. In addition, during 2010, we earned \$11,000,000 in contingent payments upon Debiopharm's successful achievement of clinical objectives, including the approval from French regulatory authorities of Debiopharm's clinical trial application, or CTA, to begin phase I clinical trials and the treatment of the fifth patient in this trial. We are eligible to receive up to an additional \$77,000,000 if specified clinical development and regulatory approval objectives are met. We are also eligible to receive royalties if any products under the license agreement are successfully developed and commercialized. For net sales of Debio 0932 that are made directly by Debiopharm, we are entitled to a high single digit to low double digit royalty, which escalates within this range with increasing product sales. In certain specified circumstances, the royalty rate applicable to Debio 0932 may be reduced. We believe that it is more likely that Debiopharm will sublicense Debio 0932 following its further development, and in this case we are entitled to a share of royalties that Debiopharm receives from such sublicensee.

The agreement is effective as of August 5, 2009, and unless terminated earlier will expire, on a country-by-country basis, on the later of (i) the expiration of the last-to-expire valid claim of the Curis patents and joint patents relating to the products, and (ii) the 10<sup>th</sup> anniversary of the first commercial sale of the product in such country. Debiopharm may terminate the agreement prior to its expiration at any time for any scientific, technical, administrative or commercial reasons upon 90 days' prior written notice to us. If Debiopharm is permanently enjoined from exercising its license under the agreement pursuant to a patent infringement action brought by a third party, or if neither Debiopharm nor we undertake the defense or settlement of a third party suit alleging infringement within the six-month period after notice of such suit, then Debiopharm may terminate the agreement in the country where such suit was filed upon thirty days' prior written notice to us. If Debiopharm does not correct a failure to use reasonable commercial efforts as set forth in the agreement, we may terminate the agreement on thirty days' written notice to Debiopharm unless Debiopharm cures such failure before the end of such thirty day period. Either party may terminate the agreement prior to its expiration subject to certain conditions, upon ninety days' (or forty-five days' in the case of failure to make payment of amounts due under

the agreement) prior written notice to the other party in the event of the material breach of any term or condition of the agreement by the other party, unless the breaching party has cured such breach by the end of the applicable cure period; and immediately upon written notice to the other party if the other party or its affiliate directly, or through assistance granted to a third party, challenges, whether as a claim, a cross-claim, counterclaim, or defense, the validity or enforceability of any of such party's patents before any court, arbitrator, or other tribunal or administrative agency in any jurisdiction.

### **Corporate Information**

We were organized as a Delaware corporation in February 2000. We began our operations in July 2000 upon the completion of the merger of Creative BioMolecules, Inc., Ontogeny, Inc. and Reprogenesis, Inc. Our principal executive office is located at 4 Maguire Road, Lexington, MA 02421 and our telephone number is (617) 503-6500.

Curis™ is our trademark and Erivedge is a trademark of Genentech. This annual report on Form 10-K may also contain trademarks and trade names of others.

### **Website Access to Reports**

We maintain a website with the address [www.curis.com](http://www.curis.com). We are not including the information contained in our website as part of, or incorporating it by reference into, this annual report on Form 10-K. Our website address is included in this annual report on Form 10-K as an inactive textual reference only. We make available free of charge through our website our annual reports on Form 10-K, our quarterly reports on Form 10-Q, current reports on Form 8-K and any such amendments to those reports as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the Securities and Exchange Commission. The Securities and Exchange Commission maintains a website, [www.sec.gov](http://www.sec.gov), that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. The public may read and copy any materials we file with the Securities and Exchange Commission at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. In addition, we provide paper copies of our filings free of charge upon request. The public may obtain information on the operation of the public reference room by calling 1-800-SEC-0330. We also make available on our website our corporate governance guidelines, the charters for our audit committee, compensation committee and nominating and corporate governance committee, and our code of business conduct and ethics, and such information is available in print to any stockholder of Curis who requests it.

### **Intellectual Property**

Our policy is to obtain and enforce the patents and proprietary technology rights that are key to our business. We intend to continue to file U.S. and foreign patent applications to protect technology, inventions and improvements that are considered important to the development of our business. We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets.

In the U.S., we have 83 issued or allowed patents expiring on various dates between 2013 and 2028 as well as numerous pending patent applications. We have foreign counterpart patent filings for most of our U.S. issued patents and patent applications. These patents and patent applications are directed to various inventions including compositions of matter, methods of making and using these compositions for multiple applications, methods for drug screening and discovery, developmental biological processes, and patents which relate to our proprietary technologies.

*Hedgehog Pathway.* We have 72 issued U.S. patents or allowed U.S. applications expiring on various dates between 2013 and 2028, which relate to the Hedgehog pathway. Our patents and patent applications cover proteins, nucleic acids, antibodies, and certain small molecule agonists and inhibitors of the Hedgehog pathway,



drug screening and discovery methods, methods of protein manufacturing, as well as methods of using the aforementioned proteins, nucleic acids, antibodies or small molecules to activate or inhibit the Hedgehog pathway for a variety of therapeutic indications or diagnostic uses. In addition, we have filed foreign patent applications corresponding to many of the aforementioned U.S. filings that could provide additional patent protection for products that activate or inhibit the Hedgehog pathway.

Our academic and research institution collaborators have certain rights to publish data and information regarding their discoveries to which we have rights. While we believe that the prepublication access to the data developed by our collaborators pursuant to our collaboration agreements will be sufficient to permit us to apply for patent protection in the areas in which we are interested in pursuing further research, there is considerable pressure on such institutions to rapidly publish discoveries arising from their efforts. This may affect our ability to obtain patent protection in the areas in which we may have an interest. In addition, these collaboration agreements typically contain provisions that provide us with, at a minimum, an option to license the institution's rights to intellectual property arising from the collaboration.

*Network-Targeted Cancer Drug Development Platform.* We have eight issued or allowed U.S. patents which expire in 2027 and 2028 and several U.S. provisional patent applications and U.S. and foreign utility patent applications directed to our targeted inhibitor classes of novel small molecules, as well as U.S. and foreign patent applications which generically claim the platform concept itself. Our patents and patent applications cover compositions of matter, methods of manufacturing these molecules, formulations, and methods of using these molecules to treat a variety of therapeutic indications. We intend to continue to file additional U.S. and foreign applications as the programs progress.

We are party to various license agreements that give us rights to commercialize various technologies, particularly our Hedgehog pathway technologies, and to use technologies in our research and development processes. The consideration payable in exchange for these licenses includes up-front fees, issuances of shares of common stock, annual royalties, milestone payments and royalties on net sales by our sub-licensees and us. The licensors may terminate these agreements if we fail to meet certain diligence requirements, fail to make payments or otherwise commit a material breach that is not cured after notice.

In addition, we depend upon trade secrets, know-how and continuing technological advances to develop and maintain our competitive position. To maintain the confidentiality of trade secrets and proprietary information, we require our employees, scientific advisors, consultants and collaborators, upon commencement of a relationship with us, to execute confidentiality agreements and, in the case of parties other than our research and development collaborators, to agree to assign their inventions to us. These agreements are designed to protect our proprietary information and to grant us ownership of technologies that are developed in connection with their

## **Research and Development Program**

We have a research group that seeks to identify and develop new therapeutic products and applications thereof for our existing proprietary portfolio and seeks to identify novel compounds able to modulate additional signaling pathways that may have therapeutic potential. As of December 31, 2011, our research and development group consists of 25 employees, consisting of molecular biologists, cell biologists, chemists, pharmacologists and other scientific disciplines. We have also engaged approximately 16 medicinal chemists on a contract basis at a contract research organization in China.

The estimated amounts spent on company-sponsored research and development activities for the years ended December 31, 2011, 2010 and 2009 were \$13,693,000, \$11,373,000 and \$9,933,000, respectively. We had no collaborator-sponsored research and development expense for the years ended December 31, 2011, 2010 and 2009 as all research funding under collaborations concluded in 2008.

## Regulatory Matters

### *FDA Requirements for New Drug Compounds*

Numerous governmental authorities in the U.S. and other countries extensively regulate, among other things, the research, testing, manufacture, import and export and marketing of drug products. In the U.S., drugs are subject to rigorous regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, labeling, promotion, sampling and marketing and distribution of pharmaceutical products. Failure to comply with applicable regulatory requirements may subject a company to a variety of administrative or judicially imposed sanctions. These sanctions could include, among other things, the FDA's refusal to approve pending applications, withdrawal of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of our operations, injunctions, fines, civil penalties or criminal prosecution.

The steps ordinarily required before a new pharmaceutical product may be marketed in the U.S. include preclinical laboratory tests, animal tests and formulation studies under the FDA's good laboratory practice, or GLP, regulations; the submission to the FDA of an investigational new drug application, or an IND, which must become effective before testing in humans, or clinical testing, may commence; approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated; adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought; submission to the FDA of a new drug application, or NDA, seeking approval to market the drug product; satisfactory completion of an FDA advisory committee review, if applicable; satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practice, or cGMP, requirements; and FDA review and approval of the NDA. Satisfaction of FDA pre-market approval requirements typically takes years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. Success in early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, later discovery of previously unknown problems with a product, including new safety risks, may result in restrictions on the product or even complete withdrawal of the product from the market.

Preclinical tests include laboratory evaluation of product chemistry and formulation, as well as animal trials to assess the potential safety and efficacy of the product. The conduct of the preclinical tests and formulation of compounds for testing must comply with federal regulations and requirements, including the FDA's GLP regulations. Preclinical testing is highly uncertain and may not be completed successfully within any specified time period, if at all. Further, the successful completion of preclinical trials does not assure success in human clinical trials. The results of preclinical testing are submitted to the FDA as part of an IND application, together with manufacturing information, analytical and stability data of the drug formulation, and other information. The IND application must become effective before clinical trials can begin in the United States. An IND application becomes effective 30 days after receipt by the FDA unless before that time the FDA places a clinical hold on the trials. In that case, the IND application sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. If these concerns or questions are unresolved, the FDA may not allow the clinical trials to commence.

Clinical trials involve the administration of the investigational drug to healthy human volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations and requirements, including good clinical practices, under protocols detailing, among other things, the objectives of the trial, the parameters to be used in assessing safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. subjects must be submitted to the FDA as part of the IND application. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap or be combined. In phase I, the initial introduction of the drug into human subjects, the drug is tested to assess metabolism, pharmacokinetics and pharmacological actions and safety, including side effects associated with increasing doses and, if possible, early evidence of effectiveness. Phase II usually involves trials in a limited patient population, to determine dosage tolerance and optimum dosage, identify possible adverse effects and safety risks, and provide preliminary support for the efficacy of the drug in the indication being studied. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in phase II evaluations, phase III trials may be undertaken to further evaluate clinical efficacy and to further test for safety within an expanded patient population, typically at geographically dispersed clinical trial sites to establish the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. Phase I, phase II or phase III testing of any drug candidates may not be completed successfully within any specified time period, if at all. The FDA closely monitors the progress of each of the three phases of clinical trials that are conducted in the U.S. The FDA may, at its discretion, reevaluate, alter, suspend or terminate the testing based upon the data accumulated to that point and the FDA's assessment of the risk/benefit ratio to the subject. The FDA, an IRB, or a clinical trial sponsor may suspend or terminate clinical trials at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. The FDA can also request that additional clinical trials be conducted as a condition to product approval. Finally, sponsors are required to publicly disseminate information about ongoing and completed clinical trials on a government website administered by the National Institutes of Health, or NIH, and are subject to civil money penalties and other civil and criminal sanctions for failing to meet these obligations.

After successful completion of the required clinical testing, generally an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of extensive preclinical and clinical testing, a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls, and proposed labeling, among other things. In most cases, a substantial user fee must accompany the NDA. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission before accepting them for filing to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals regarding the timing of its review of NDAs, although the FDA does not always meet these goals. The FDA may also refer applications for novel drugs or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP and integrity of the clinical data submitted.

If the FDA's evaluation of the NDA and inspection of the manufacturing facilities are favorable, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require post-approval testing, including phase IV trials, and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling restrictions and restrictions on distribution and use of the drug, which can materially impact the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Once the NDA is approved, a product will be subject to certain post-approval requirements, including requirements for adverse event reporting, submission of periodic reports, and drug sampling and distribution requirements. If new safety issues arise after approval, the FDA may require the company to conduct additional post-market studies to assess the risk, change the labeling to address the risk, or impose distribution and use restrictions under a Risk Evaluation and Mitigation Strategy, or REMS. Additionally, the FDA strictly regulates the promotional claims that may be made about prescription drug products. In particular, a drug may not be promoted for uses that are not approved by the FDA as reflected in the drug's approved labeling. Moreover, the Department of Justice can bring civil or criminal actions against companies that promote drugs for unapproved uses, based on the Federal Food, Drug, and Cosmetic Act, the False Claims Act and other federal laws governing reimbursement for drugs under the Medicare and Medicaid laws. Monetary penalties in such cases have often been in excess of \$100 million and in some cases have exceeded \$1 billion. In addition, the FDA requires substantiation of any claims of superiority of one product over another including, in many cases, requirements that such claims be proven by adequate and well-controlled head-to-head clinical trials. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to FDA review and approval of a new NDA or NDA supplement before the change can be implemented. Manufacturing operations must continue to conform to cGMPs after approval. Drug manufacturers are required to register their facilities with the FDA and are subject to periodic unannounced inspections by the FDA to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

If the FDA's evaluation of the NDA submission or manufacturing facilities is not favorable, the FDA may refuse to approve the NDA or issue a complete response letter. The complete response letter outlines the deficiencies in the submission and may require additional testing or information in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. With limited exceptions, the FDA may withhold approval of a NDA regardless of prior advice it may have provided or commitments it may have made to the sponsor.

#### *Foreign Regulation of New Drug Compounds*

Approval of a drug product by comparable regulatory authorities will be necessary in foreign countries prior to the commencement of marketing of the product in those countries, whether or not FDA approval has been obtained. While clinical data generated in the U.S. may be accepted in many foreign jurisdictions in lieu of early stage clinical trials (phase I), the approval procedure varies among countries and can involve requirements for additional testing equivalent to phases II and III. The time required may differ from that required for FDA approval and may be longer than that required to obtain FDA approval. There can be substantial delays in obtaining required approvals from foreign regulatory authorities after the relevant applications are filed.

In Europe, marketing authorizations may be submitted under a centralized or decentralized procedure. The centralized procedure is mandatory for the approval of biotechnology products and many pharmaceutical products, and provides for the grant of a single marketing authorization, which is valid in all European Union member states. The decentralized procedure is a mutual recognition procedure that is available at the request of the applicant for medicinal products that are not subject to the centralized procedure.

#### *Hazardous Materials*

Our research and development processes involve the controlled use of hazardous materials, chemicals and radioactive materials and produce waste products. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products.

## Competition

Our drug candidates, if approved, will compete with existing and new products being developed by others for treatment of the same indications. Competition in the development of human therapeutics and, in particular, human therapeutics that target signaling pathways to treat cancers, is intense. Our competitors include large pharmaceutical and biopharmaceutical companies, as well as specialized biotechnology firms, that are developing cancer therapies in the same indications as we are.

*Hedgehog Pathway Inhibitor Program.* We are aware of several biotechnology and pharmaceutical companies that have drug development programs relating to compounds that modulate the Hedgehog pathway. We believe that there are currently at least five other companies that have progressed Hedgehog pathway inhibitors into clinical development: Infinity Pharmaceuticals, Inc.; Exelixis, Inc. (in co-development with the Bristol-Myers Squibb Company); Pfizer Inc.; Novartis International AG; and Millennium Pharmaceuticals.

*Network-Targeted Cancer Programs.* There are several companies developing drug candidates that target the same cancer pathways that we are also targeting or that are testing drug candidates in the same cancer indications that we are testing through our proprietary network-targeted cancer programs. We believe that our competitive advantage over these companies is our strategy of developing drug candidates that target unique combinations of these cancer pathways to achieve synergistic effect. For example, several companies are investigating Hsp90 inhibitors in clinical testing, including, among others Bristol-Myers Squibb Company, Novartis International AG, Pfizer Inc., Astex Therapeutics Ltd., Myriad Pharmaceuticals Inc., Kyowa Hakko Kirin Co, Ltd., Daiichi Sankyo, and Synta Pharmaceuticals Corp. There are commercially-available drugs that individually target either HDAC or EGFR as well as a drug that targets EGFR/Her2. There are also several drug candidates in clinical testing that are designed to inhibit one or more of these targets. However, we are not aware of other molecules in clinical testing that are designed to simultaneously target HDAC, EGFR and Her2 simultaneously.

Many of the companies competing against us have financial, marketing and human resource capacities that are substantially greater than our own, which may provide these competitors with significant competitive advantages over us. Others have extensive experience in undertaking clinical trials, in obtaining regulatory approval to market products, in manufacturing products on a large scale and in effectively promoting products to healthcare providers, health plans and consumers which may enhance their competitive position relative to ours. In addition to competing with pharmaceutical and biotechnology companies, the products we are developing would also compete with those being developed by academic and research institutions, government agencies and other public organizations. Any of these organizations may discover new therapies, seek patent protection or establish collaborative arrangements for products and technologies that are competitive with our products and technologies.

The technologies underlying the development of human therapeutic products are expected to continue to undergo rapid and significant advancement and unpredictable changes. Accordingly, our technological and commercial success will be based, among other things, on our ability to develop proprietary positions in key scientific areas and efficiently evaluate potential product opportunities.

The timing of a product's introduction may be a major factor in determining eventual commercial success and profitability. Early entry may have important advantages in gaining product acceptance and market share. Accordingly, we believe the relative speed with which we or any current or future collaborator can complete preclinical and clinical testing, obtain regulatory approvals, and supply commercial quantities of a product will have an important impact on our competitive position, both in the U.S. and abroad. Other companies may succeed in developing similar products that are introduced earlier, are more effective, or are produced and marketed more effectively, or at a minimum obtain a portion of the market share. For example, our competitors may discover, characterize and develop important targeted cancer molecules before we do, which could have a material adverse effect on any of our related research programs. If research and development by others renders any of our products obsolete or noncompetitive, then our potential for success and profitability may be adversely affected.

For certain of our programs, we rely on, or intend to rely on, strategic collaborators for support in our research programs and for preclinical evaluation and clinical development of our potential products and manufacturing and marketing of any products. Our strategic collaborators may conduct multiple product development efforts within each disease area that is the subject of our strategic collaboration with them. Our strategic collaboration agreements may not restrict the strategic collaborator from pursuing competing internal development efforts. Any of our drug candidates, therefore, may be subject to competition with a drug candidate under development by a strategic collaborator.

### **Manufacturing**

We have no experience or capabilities in manufacturing. We currently rely on collaborators or subcontractors, and we have no plans to develop our own manufacturing capability. Instead, we plan to continue to rely on corporate collaborators or subcontractors to manufacture products. If any of our current or planned collaborators or subcontractors encounters regulatory compliance problems or enforcement actions for their own or a collaborative product, it could have a material adverse effect on our business prospects.

### **Sales and Marketing**

We have no sales, marketing or distribution experience or infrastructure and we have no current plans to develop sales, marketing and distribution capabilities. We currently plan to rely on corporate collaborators for product sales, marketing and distribution.

### **Employees**

As of December 31, 2011, we had 35 full-time employees, of whom 11 hold a Ph.D. or other advanced degree. Of our employees, 25 are currently involved in research and development. None of our employees is a party to a collective bargaining agreement, and we consider our relations with our employees to be good.

### **Clinical and Scientific Advisory Board**

We have established a clinical and scientific advisory board that is comprised of physicians in the field of cancer research and drug development. Members of this board consult with us on matters relating to our research and development programs, including clinical trial design, new technologies relevant to our research and development programs and other scientific and technical issues relevant to our business. In addition to these permanent committee members, the clinical and scientific advisory board from time-to-time engages outside experts, including, for example key opinion leaders in specific cancers targeted by our drug candidates.

The current members of our clinical and scientific advisory board are as follows:

#### **Kenneth J. Pienta, M.D. (Chairman)**

Kenneth J. Pienta, M.D., professor of medicine and urology, is the Director of Experimental Therapeutics for the Michigan Center for Translational Pathology. In this role, he oversees the implementation of precision medicine to the care of patients suffering from cancer. He also serves as director for the Specialized Program of Research Excellence (SPORE) grant in prostate cancer at the University of Michigan Comprehensive Cancer Center. As the principal investigator of the \$12,000,000 National Cancer Institute grant, Dr. Pienta is responsible for overseeing multidisciplinary efforts to prevent, diagnose and treat prostate cancer.

Dr. Pienta's research interests include understanding the ecology of the tumor microenvironment. His laboratory focuses on understanding the process of prostate cancer metastasis to bone and discovering novel drug combinations to treat prostate cancer.

Dr. Pienta joined the University of Michigan Comprehensive Cancer Center in 1994. Previously, he was assistant professor at Wayne State University School of Medicine and deputy director of the Urologic Oncology Program at the Meyer L. Prentis Comprehensive Cancer Center in Detroit. He received his medical degree and was a postdoctoral fellow at Johns Hopkins University in Baltimore.

**Philip A. Philip, M.D., Ph.D., F.R.C.P.**

Philip A. Philip, M.D., Ph.D., F.R.C.P., is a Professor of Oncology at Wayne State University School of Medicine and the Barbara Ann Karmanos Cancer Institute in Detroit, Michigan. He directs the gastrointestinal cancer program. He is certified by the American Board of Internal Medicine in both Internal Medicine and Medical Oncology. He is also a fellow of the Royal College of Medicine in the United Kingdom. Dr. Philip's primary research focus is in the clinical trials of novel therapeutic agents and therapeutic combinations on patients with pancreatic, gastro-esophageal, hepatobiliary, neuroendocrine and colorectal cancer. He is actively involved in phase I-III clinical trials with experience as a principal investigator in many trials. He is an active researcher at the national level in the cooperative group mechanism. He has also served on steering committees and data safety monitoring committees of several global studies. He belongs to numerous national and international professional and scientific organizations including the American pancreatic Association, Southwest Oncology Group, International Liver Cancer Association and the American Society of Clinical Oncology.

Dr. Philip serves on the Editorial Board of several cancer journals and reviews for multiple high impact factor impact, including the Journal of Clinical Oncology and the European Journal of Cancer. He has authored over 130 articles in peer-reviewed journals, seven book chapters and many invited review articles. He has also written several invited editorials and co-edited a book on pancreas cancer.

Dr. Philip received his B.A. from the American Jesuits Fathers College in Baghdad, Iraq, M.D. from the University of Baghdad College of Medicine and Ph.D. in Clinical Pharmacology and Pharmacogenetics from the University of London, UK. He trained in oncology at the University of London, the University of Oxford, UK and the MD Anderson Cancer Center in Houston.

**Samir E. Witta, M.D., Ph.D.**

Samir E. Witta, M.D., Ph.D., launched the Mountain Blue Cancer Care Center in 2009. Dr. Witta specializes in medical oncology and practices at the Mountain Blue Cancer Care Center. He is a Clinical Assistant Professor at the University of Colorado where he is involved in translational research. Dr. Witta received his M.D. from the First Faculty of Medicine, Charles University in Prague. Dr. Witta earned his Ph.D. in genetics and developmental biology from the First Faculty of Medicine, Charles University and from the National Institutes of Health in Bethesda, Maryland. Dr. Witta completed his residency in internal medicine at The Northeastern Pennsylvania Affiliated Residency Program. He then did a fellowship in hematology and medical oncology at the University of Colorado Health Sciences Center in Denver. Dr. Witta is a member of the American Society of Clinical Oncology and the president of the Rocky Mountain Oncology Society.

## Executive Officers of the Registrant

Our executive officers are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Daniel R. Passeri, MSc., J.D.	51	President and Chief Executive Officer
Michael P. Gray . . . . .	41	Chief Operating Officer and Chief Financial Officer
Mark W. Noel . . . . .	53	Vice President, Technology Management and Intellectual Property
Maurizio Voi, M.D . . . . .	54	Chief Medical Officer and Chief Development Officer
Daniel R. Passeri, MSc., J.D.	Mr. Passeri has served as our President and Chief Executive Officer and as a director since September 2001. From November 2000 to September 2001, Mr. Passeri served as our Senior Vice President, Corporate Development and Strategic Planning. From March 1997 to November 2000, Mr. Passeri was employed by GeneLogic Inc., a biotechnology company, most recently as Senior Vice President, Corporate Development and Strategic Planning. From February 1995 to March 1997, Mr. Passeri was employed by Boehringer Mannheim, a pharmaceutical, biotechnology and diagnostic company, as Director of Technology Management. Mr. Passeri is a graduate of the National Law Center at George Washington University, with a J.D., of the Imperial College of Science, Technology and Medicine at the University of London, with an M.Sc. in biotechnology, and of Northeastern University, with a B.S. in biology.	
Michael P. Gray . . . . .	Mr. Gray has served as our Chief Operating Officer and Chief Financial Officer since December 2006. From December 2003 until December 2006, Mr. Gray served as our Vice President of Finance and Chief Financial Officer and served as our Senior Director of Finance and Controller from August 2000 until December 2003. From January 1998 to July 2000, Mr. Gray was Controller at Reprogenesis, Inc., a predecessor biotechnology company. Mr. Gray previously served as an audit professional for the accounting and consulting firm of Ernst & Young, LLP. Mr. Gray is a certified public accountant, holds an M.B.A. from the F.W. Olin Graduate School of Business at Babson College, and has a B.S. in accounting from Bryant College.	
Mark W. Noel . . . . .	Mr. Noel has served as our Vice President, Technology Management and Intellectual Property since September 2008. From March 2001 until September 2008, Mr. Noel has served as our Vice President, Technology Management and Business Development. From March 2000 to February 2001, Mr. Noel was employed by GeneLogic, as Vice President of Customer Relations. From January 1998 to February 2000, Mr. Noel was employed by GeneLogic as Senior Director of Program Management. From December 1993 to January 1998, Mr. Noel was employed by the U.S. Department of Human Services National Cancer Institute Office of Technology Development (now the NCI Technology Transfer Center), where from July 1997 to January 1998, he served as Acting Deputy Director. From February 1989 to November 1993, Mr. Noel worked as a patent agent at Gist Brocades NV, a supplier of ingredients to the pharmaceutical and food sectors. Mr. Noel holds a B.S. from the University of Maryland.	
Maurizio Voi, M.D . . . . .	Dr. Voi has served as our Chief Medical and Chief Development Officer since November 2011. From October 2009 until November 2011, Dr. Voi was employed by Pfizer, Inc., a pharmaceutical company, as Vice President of Clinical Development and Medical Affairs at the Oncology Business Unit of Pfizer's Global Research and Development site in New York. Dr. Voi joined Pfizer in November 2009 as Thoracic Tumor Strategy Team Leader for Oncology. Prior to joining Pfizer, Dr. Voi served from 1998 to 2009 in several key positions at Bristol-Myers Squibb Company, a pharmaceutical company, most recently as the Executive Director, Global Clinical Development and Medical Affairs, Oncology. From 1987-1999, he served in several roles at Eli Lilly and Company, a pharmaceutical company. Dr. Voi holds an M.D. from the University of Padua, School of Medicine in Italy and practiced medicine at the General Hospital, Dolo in Venice, Italy.	



## ITEM 1A. RISK FACTORS

### RISKS RELATING TO THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS

**We are reliant on Genentech for the successful development and commercialization of Erivedge. If Genentech does not successfully commercialize Erivedge for advanced BCC, or develop Erivedge for other indications, our future prospects and our ability to finance our operations may be substantially harmed.**

In January 2012, Erivedge was approved by the FDA as the first and only FDA-approved medicine for people with advanced forms of BCC. Genentech has also filed and had accepted an MAA with the EMA seeking regulatory approval of Erivedge in the EU for this same indication. Genentech and Roche are also conducting a phase II clinical trial of Erivedge in operable nodular BCC and Erivedge is currently being tested in other cancers under collaborative agreements between Genentech and either third-party investigators or the NCI. Our near-term prospects substantially depend upon Genentech's ability to successfully develop and commercialize Erivedge in one or more indications and to demonstrate its safety and efficacy, as well as its superiority over existing therapies and standards of care. Moreover, our ability to finance our company and to generate revenues will depend heavily on the ability of Genentech and Roche to: (i) derive meaningful royalties from the commercial sale of Erivedge for advanced BCC, (ii) successfully file regulatory submissions for, and obtain approval to sell, Erivedge in Europe and/or other territories for advanced BCC, and (iii) obtain favorable results in ongoing and planned clinical trials of Erivedge in other indications, including the ongoing clinical trial in operable BCC. The development and commercialization of Erivedge could be unsuccessful if:

- Erivedge for the treatment of advanced BCC is not accepted as safe, efficacious, cost-effective, less costly and preferable to current therapies in the medical community and by third-party payors;
- Genentech fails to apply the necessary financial resources and expertise to manufacturing, marketing and selling Erivedge for advanced BCC and to regulatory approvals for this indication outside of the US;
- Genentech does not develop and implement effective marketing, sales and distribution strategies and operations, for development and commercialization of Erivedge for advanced BCC;
- Genentech does not develop, validate and maintain a commercially viable manufacturing process for Erivedge that is compliant with current good manufacturing practices, or cGMP;
- Genentech does not successfully obtain third party reimbursement and generate commercial demand that results in sales of Erivedge for advanced BCC in any geographic areas where requisite approvals have been, or may be, obtained;
- we or Genentech encounter any third party patent interference or patent infringement claims with respect to Erivedge;
- Genentech does not comply with any and all regulatory and legal requirements applicable to the sale of Erivedge for advanced BCC;
- new safety risks are identified after Erivedge is commercially marketed; and/or
- Erivedge does not demonstrate acceptable safety and efficacy in current or future clinical trials, or otherwise does not meet applicable regulatory standards for approval in indications other than advanced BCC.

**The therapeutic efficacy of drug candidates being developed in our network-targeted cancer programs is unproven in humans, and we may not be able to successfully develop and commercialize CUDC-101 or any other future drug candidates that we may select from these programs.**

Our drug candidates in our network-targeted cancer program, including CUDC-101, Debio 0932 and CUDC-907, are novel compounds and their potential benefit as therapeutic cancer drugs is unproven. These drug candidates may not prove to be effective inhibitors of the validated cancer targets they are being designed to act against and

may not demonstrate in patients any or all of the pharmacological benefits that we believe they may possess or that may have been demonstrated in preclinical studies. Moreover, there is a risk that these drug candidates may interact with human biological systems in unforeseen, ineffective or harmful ways. As a result of these and other risks described herein that are inherent in the development of novel therapeutic agents, we may never successfully develop, enter into or maintain third party licensing or collaboration transactions with respect to, or successfully commercialize CUDC-101, CUDC-907 or Debio 0932, or any other drug candidates from our network-targeted cancer programs, in which case we will not achieve profitability and the value of our stock will decline.

**We depend on third parties for the development of certain of our programs. If one or more of our collaborators fails or delays in developing or commercializing drug candidates based upon our technologies, our business prospects and operating results would suffer and our stock price would likely decline.**

We currently have a collaboration with Genentech pursuant to which we have granted to Genentech exclusive rights to develop and commercialize products based upon our Hedgehog pathway technologies. Genentech recently obtained FDA approval to commercialize Erivedge, the sole compound being developed under this collaboration, in advanced BCC. Genentech is also seeking to obtain regulatory approval for this same indication in the EU, and is also conducting, both alone and in collaboration, further studies of Erivedge for other indications. In addition, we entered into a license agreement with Debiopharm pursuant to which Debiopharm is testing Debio 0932 in a phase Ib clinical trial in advanced solid tumors. Our collaboration agreement with Genentech and our license agreement with Debiopharm are our most significant collaborations, and these collaborations may not be scientifically or commercially successful due to a number of factors, including the following:

- Genentech and Debiopharm each have significant discretion in determining the efforts and resources that they will apply to their respective collaboration with us. The timing and amount of any cash payments related to royalties and the achievement of development objectives that we may receive under such collaborative arrangements will depend on, among other things, our collaboration partners' efforts, allocation of resources and successful development and commercialization of our drug candidates under their respective agreements with us. For example, our ability to obtain meaningful amounts of royalty income from sales of Erivedge for advanced BCC will depend solely upon the degree to which Genentech applies suitable financial and other resources to the manufacture, commercialization and sale of Erivedge for advanced BCC and to obtaining regulatory approvals outside of the US.
- Our agreements with Genentech and Debiopharm each permits the other party wide discretion in deciding which drug candidates to advance through the clinical trial process. It is possible for Genentech or Debiopharm to reject drug candidates at any point in the research, development and clinical trial process, without triggering a termination of the applicable agreement. In the event of any such decision, our business and prospects may be adversely affected and we may not have the commercial rights or the resources necessary to advance such programs on our own.
- We have granted clinical development rights to Genentech and Debiopharm, respectively, under our agreements with each of them. If they fail to allocate sufficient time, attention and resources to clinical trials of product candidates under these collaborations, or fail to comply with good clinical practices or other applicable regulatory requirements for such clinical trials, the successful clinical development and commercialization of such product candidates is likely to be adversely affected, as will our ability to generate revenue from such collaborations.
- Either Genentech or Debiopharm may develop and commercialize, either alone or with others, products that are similar to or competitive with the drug candidates that are the subject of its collaboration with us. For example, Genentech and Debiopharm each are developing several other programs in cancer.
- Either Genentech or Debiopharm may change the focus of its development and commercialization efforts or pursue higher-priority programs. Our ability to successfully commercialize drug candidates under collaboration with Genentech or Debiopharm could be limited if Genentech or Debiopharm decreases or fails to increase spending related to such drug candidates.

- Either Genentech or Debiopharm may enter into one or more transactions with third parties, including a merger, consolidation, reorganization, sale of substantial assets, sale of substantial stock or change of control. For example, during the first quarter of 2009, Roche Holdings Ltd. completed its acquisition of Genentech. Any such transaction could divert the attention of our collaborative partner's management and adversely affect its ability to retain and motivate key personnel who are important to the continued development of the programs under such collaboration. In addition, an acquirer could determine to reprioritize our collaborator's development programs such that our collaborator ceases to diligently pursue the development of our programs, and/or terminates its collaboration with us.
- Either Genentech or Debiopharm may, under specified circumstances, terminate its collaboration with us on short notice and for circumstances outside of our control, which could make it difficult for us to attract new collaborators or adversely affect how we are perceived in the scientific and financial communities.
- Both Genentech and Debiopharm have the first right to maintain or defend our intellectual property rights under their respective agreements and, although we may have the right to assume the maintenance and defense of our intellectual property rights if our collaborators do not, our ability to do so may be compromised by our collaborators' acts or omissions.
- Either Genentech or Debiopharm may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability.
- Either Genentech or Debiopharm may not comply with all applicable regulatory requirements, or fail to report safety data in accordance with all applicable regulatory requirements.
- If either Genentech or Debiopharm were to breach or terminate its arrangement with us, the development and commercialization of the affected product candidate could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue development and commercialization of the product candidate on our own.
- Either Genentech or Debiopharm may not have sufficient resources necessary to advance clinical development of product candidates under our collaborations with each of them or may not obtain the necessary regulatory approvals.

If Genentech or Debiopharm fails to successfully develop and commercialize our drug candidates under collaboration, we may not be able to develop and commercialize these candidates independently or successfully enter into one or more alternative collaborations, in which event our financial condition, results of operations and stock price may be adversely affected.

For a further discussion of risks relating specifically to our dependence on Genentech for the successful development and commercialization of Erivedge, see: "We are reliant on Genentech for the successful development and commercialization of Erivedge. If Genentech does not successfully commercialize Erivedge for advanced BCC, or develop Erivedge for other indications, our future prospects and our ability to finance our operations will be substantially harmed."

**We may not be successful in establishing additional strategic collaborations, which could adversely affect our ability to develop and commercialize products.**

Our current strategy is to seek corporate collaborators or licensees for the further development and commercialization of one or more drug candidates under our network-targeted cancer drug programs, generally following our completion of at least phase I clinical testing. For example, while we are not presently seeking to enter into corporate collaborations for CUDC-101, we are likely to seek to partner CUDC-101, CUDC-907 as well as other drug candidates from these programs in the future. We do not currently have the experience, resources or capacity to advance these programs into later stage clinical development (i.e., phase III) or commercialization. As such, our success will depend, in part, on our ability to enter into one or more such

collaborations. We face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for CUDC-101, CUDC-907 or any future programs because our research and development pipeline may be insufficient, our programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our drug candidates and programs as having the requisite potential to demonstrate safety and efficacy or sufficient differentiability compared to existing or emerging treatments. Even if we are successful in our efforts to establish new collaborations, the terms that we agree upon may not be favorable to us.

Moreover, if we fail to establish and maintain additional strategic partnerships related to our product candidates:

- the development of certain of our current or future product candidates may be terminated or delayed;
- our cash expenditures related to development of certain of our current or future product candidates would increase significantly and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise develop expertise, such as additional clinical, regulatory, sales and marketing expertise, for which we have not budgeted;
- we will bear all of the risk related to the development of any such product candidates; and
- our future prospects may be adversely affected and our stock price could decline.

**If preclinical studies and clinical trials of our drug candidates are not successful then our future profitability and success could be adversely affected.**

In order to obtain regulatory approval for the commercial sale of our drug candidates, we and any current or potential future collaborators will be required to complete extensive preclinical studies as well as clinical trials in humans to demonstrate to the FDA and foreign regulatory authorities that our drug candidates are safe and effective for each indication for which approval is sought.

Development, including preclinical and clinical testing, is a long, expensive and uncertain process. Preclinical testing and clinical trials of our drug candidates may not be successful. We and our collaborators could experience delays or failures in preclinical testing or clinical trials of any of our drug candidates for a number of reasons including, for example:

- preclinical studies or clinical trials may produce negative, inconsistent or inconclusive results, as occurred in Genentech's phase II clinical trials of Erivedge in colorectal cancer and ovarian cancer, both of which were completed in 2010;
- we or any collaborators may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or terminate testing for a particular drug candidate;
- the results from preclinical studies and early clinical trials may not be statistically significant or predictive of results that will be obtained from expanded, advanced clinical trials;
- we may encounter difficulties or delays in manufacturing sufficient quantities of the drug candidate used in any preclinical study or clinical trial;
- the timing and completion of clinical trials of our drug candidates depend on, among other factors, the number of patients required to be enrolled in the clinical trials and the rate at which those patients are enrolled, and any increase in the required number of patients, decrease in recruitment rates or difficulties retaining study participants may result in increased costs, program delays or program termination;
- our products under development may not be effective in treating any of our network-targeted cancer indications or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may prevent or limit their commercial use;

- institutional review boards, regulators, including the FDA or its foreign equivalents, or any collaborators may hold, suspend or terminate our clinical research or the clinical trials of our drug candidates for various reasons, including failure to achieve established success criteria, noncompliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks; and
- we, along with any of our current or potential future collaborators and subcontractors, may not employ, in any capacity, persons who have been debarred under the FDA's Application Integrity Policy, or similar policy under foreign regulatory authorities, nor may we or any of our current or potential future collaborators or subcontractors use disqualified clinical investigators or institutions to perform clinical trials of our drug candidates. Employment or use of such a debarred or disqualified person or institution may result in delays in FDA's or foreign equivalent's review or approval of our products, or the rejection of data developed with the involvement of such person(s) or institution(s).

If the preclinical studies and/or clinical trials for any of our drug candidates that we and any collaborators pursue are not successful, then our ability to successfully develop and commercialize products on the basis of the respective technologies will be materially adversely affected, our reputation and our ability to raise additional capital will be materially impaired and our stock price is likely to decline.

**We expect to rely in part on third parties to conduct clinical trials of our internally-developed product candidates, and if such third parties perform inadequately then we will not be able to successfully develop and commercialize drug candidates and grow our business.**

We have a limited internal group for overseeing our clinical trials, currently comprised of our chief medical and development officer, our director of development and our clinical operations manager. In the near term, we expect to rely in part on third parties such as consultants, contract research organizations and other similar entities to complete IND-enabling preclinical studies, assist us in creating and submitting IND applications, enroll qualified subjects, conduct our clinical trials and provide services in connection with such clinical trials. Our reliance on these third parties for clinical development activities will reduce our control over these activities. These third parties may not complete activities on schedule, or at all, or may not conduct our clinical trials in accordance with the clinical trial protocol or design. In addition, the FDA and its foreign equivalents require us to comply with certain standards, referred to as good clinical practices, and applicable regulatory requirements, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. If any of the third party contractors on whom we rely do not comply with good clinical practices or other applicable regulatory requirements, we may not be able to use the data and reported results from the applicable trial. Any failure by a third party to conduct our clinical trials as planned or in accordance with regulatory requirements could delay or otherwise adversely affect our efforts to obtain regulatory approvals for and commercialize our drug candidates.

**If we and our collaborative partners do not obtain necessary regulatory approvals, then our business will be unsuccessful and the market price of our common stock could substantially decline.**

We and our collaborators will be required to obtain regulatory approval in order to successfully advance drug candidates through the clinic and prior to marketing and selling such products. The process of obtaining required regulatory approvals is expensive and the time required for these approvals is uncertain and typically takes a number of years, depending on the type, complexity and novelty of the product. With respect to our internal programs, we have limited experience in filing and prosecuting applications to obtain marketing approval.

Any regulatory approval to market a product may be subject to limitations on the approved indicated uses for which we or our collaborative partners may market the product or to distribution and use restrictions or other requirements under a Risk Evaluation and Mitigation Strategy, or REMS. These limitations may restrict the size of the market for the product and affect reimbursement by third-party payors. In addition, regulatory agencies may not grant approvals on a timely basis or may revoke or significantly modify previously granted approvals.

We and our collaborators are subject to numerous foreign regulatory requirements governing the manufacturing and marketing of potential future products outside of the United States. The approval procedure varies among countries, additional testing may be required in some jurisdictions, and the time required to obtain foreign approvals often differs from that required to obtain FDA approvals. Moreover, approval by the FDA or a foreign equivalent does not ensure approval by regulatory authorities in other countries, and vice versa.

In addition, regulatory agencies may change existing requirements or adopt new requirements or policies. We and any collaborative partners may be slow to adapt or may not be able to adapt to these changes or new requirements.

As a result of these factors, we and any collaborators may not successfully begin or complete clinical trials and/or obtain regulatory approval to market and sell drug candidates in the time periods estimated, if at all. Moreover, if we or any collaborators incur costs and delays in development programs or fail to successfully develop and commercialize products based upon our technologies, we may not become profitable and our stock price could decline.

**Even if marketing approval is obtained, any products we or any collaborators develop will be subject to ongoing regulatory oversight, which may affect the successful commercialization of such products.**

Even if we or any collaborators obtain regulatory approval of a drug candidate, the approval may be subject to limitations on the approved indicated uses for which the product can be marketed, impose restrictions on how the product can be distributed and used pursuant to a REMS, or require costly post-marketing follow-up studies. After marketing approval for any product is obtained, the manufacturer and the manufacturing facilities for that product will be subject to continual review and periodic inspections by the FDA, or foreign equivalent, and other regulatory agencies. The subsequent discovery of previously unknown problems with the product, or with the manufacturer or facility, or a failure to comply with regulatory requirements, may result in restrictions on the product or manufacturer, including withdrawal of the product from the market, fines, refusal to approve pending applications or supplements, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, refusal to permit the import or export of our products or those of our collaborators, and criminal prosecution.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our or our collaborators' product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we or they may lose any marketing approvals that have been obtained, which would adversely affect the amount of revenue generated from such products and adversely affect our ability to achieve or sustain profitability.

**We and our current collaborators are, and any potential future collaborators will be, subject to governmental regulations in connection with the research, development and commercialization of our drug candidates. We and our collaborators may not be able to comply with these regulations, which could subject us or such collaborators to penalties and result in the imposition of limitations on our or such collaborators' operations.**

In addition to regulations imposed by the FDA or foreign equivalents, we and our current collaborators are, and any potential future collaborators will be, subject to regulation under, among other laws, the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Research Conservation and Recovery Act, as well as regulations administered by the Nuclear Regulatory Commission, national restrictions on technology transfer, import, export and customs regulations and certain other local, state or federal regulations. From time to time, other federal agencies and congressional committees have indicated an

interest in implementing further regulation of pharmaceutical and biotechnology companies. We are not able to predict whether any such regulations will be adopted or whether, if adopted, such regulations will apply to our business, or whether we or any collaborators would be able to comply with any applicable regulations.

**Our business involves the use of hazardous materials and we must comply with environmental laws and regulations, which can be expensive and restrict how we do business.**

Our research and development activities involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for handling and disposing of such materials comply with all applicable laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury caused by these materials. Violation of these laws and regulations could lead to substantial fines and penalties. In the event of an accident, state or federal authorities may curtail our use of these materials and interrupt our business operations. In addition, we could become subject to potentially material liabilities relating to the investigation and cleanup of any contamination, whether currently unknown or caused by future releases.

**Our business and operations would suffer in the event of system failures.**

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our product development programs. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our product candidates may be delayed.

**If we or any of our collaborators fail to achieve market acceptance for any approved products, our future revenue and ability to achieve profitability may be adversely affected.**

Our future products, including those developed under collaborations with third parties, may not gain commercial acceptance among physicians, patients and third-party payors, even if necessary marketing approvals have been obtained. We believe that recommendations and endorsements by physicians will be essential for market acceptance of any products we or our collaborators successfully develop. If we or our collaborators are not able to obtain market acceptance for such products, our expected revenues from sales of these products would be adversely affected and our business may not be successful.

## **RISKS RELATING TO OUR FINANCIAL RESULTS AND NEED FOR FINANCING**

**We have incurred substantial losses, expect to continue to incur substantial losses for the foreseeable future and may never generate significant revenue or achieve profitability.**

As of December 31, 2011, we had an accumulated deficit of approximately \$732,088,000. We have incurred net losses of \$9,859,000, \$4,435,000 and \$9,823,000 for the years ended December 31, 2011, 2010, and 2009, respectively. Other than Erivedge, which was approved by the FDA in January 2012 for the treatment of advanced forms of basal cell carcinoma, we have not successfully commercialized any products to date, either alone or in collaboration with others. We are entitled to royalties on net sales of Erivedge by Genentech. If these royalties are not meaningful or we are not able to successfully commercialize any products, we will not achieve profitability. All of our drug candidates other than Erivedge are in early stages of development. For the foreseeable future, we will need to spend significant capital in an effort to develop and commercialize products and we expect to incur substantial operating losses. Our failure to become and remain profitable would, among other things, depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our research and development programs or continue our operations.

**We will require substantial additional capital, which is likely to be difficult to obtain.**

We will require substantial funds to continue our research and development programs and to fulfill our planned operating goals. In particular, our currently planned operating and capital requirements include the need for substantial working capital to support our research and development activities for CUDC-101, CUDC-907 and other small molecules that we are seeking to develop from our pipeline of network-targeted cancer programs, and to fund our general and administrative costs and expenses.

We have historically derived a substantial portion of our operating cash flow from the research funding portion of collaboration agreements with third parties. However, we have no current research funding revenue under collaboration agreements. Our only potential source of cash flows from operations for the foreseeable future is contingent payments that we could receive under existing or new collaborations as follows:

- up-front license payments and research and development funding that we may receive if we are able to successfully enter into new collaboration agreements for our technologies under development;
- contingent cash payments that we may receive for the achievement of development objectives under any new collaborations or our existing collaborations with Genentech and Debiopharm; and
- royalty payments that are contingent upon the successful commercialization of products based upon these collaborations, including royalties on US sales of Erivedge by Genentech in advance basal cell carcinoma.

We may not be able to successfully enter into or continue any corporate collaborations and the timing, amount and likelihood of us receiving payments under such collaborations is highly uncertain. As a result, we cannot assure you that we will attain adequate future operating capital, if any, from collaborations or licensing arrangements.

We anticipate that existing cash, cash equivalents, marketable securities and working capital at December 31, 2011 should enable us to maintain current and planned operations into the second half of 2013. Our future capital requirements, however, may vary from what we currently expect. There are a number of factors that may affect our planned future capital requirements and accelerate our need for additional working capital, many of which are outside our control, including the following:

- unanticipated costs in our research and development programs;
- the timing and cost of obtaining regulatory approvals for our drug candidates;
- the timing, receipt and amount of payments, if any, from current and potential future collaborators, including the level of any royalty payments from sales of Erivedge;
- the timing and amount of payments due to licensors of patent rights and technology used in our drug candidates;
- unplanned costs to prepare, file, prosecute, maintain and enforce patent claims and other patent-related costs, including litigation costs and technology license fees; and
- unexpected losses in our cash investments or an inability to otherwise liquidate our cash investments due to unfavorable conditions in the capital markets.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to:

- delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates; or
- delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.



**Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.**

We may seek additional funding through public or private financings of debt or equity. For example, in June 2011 we entered into an agreement with McNicoll, Lewis & Vlak, LLC, or MLV, pursuant to which, from time to time, we may offer and sell up to \$20 million of common stock through MLV pursuant to one or more “at the market” offerings. In addition, with our prior written approval, MLV may also sell these shares of common stock by any other method permitted by law, including in privately negotiated transactions. The market for emerging life science stocks in general, and the market for our common stock in particular, are highly volatile. Due to this and various other factors, including adverse general market conditions and the early-stage status of our development pipeline, additional funding may not be available to us on acceptable terms, if at all, and we may not be able to sell additional shares under the arrangement with MLV at favorable prices, if at all. In addition, the terms of any financing may be dilutive or otherwise adversely affect other rights of our stockholders. We also expect to seek additional funds through arrangements with collaborators, licensees or other third parties. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or drug candidates. Moreover, we may not be able to enter into such arrangements on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, whether through sales of debt or equity or through third party collaboration or license arrangements, we may be required to curtail or terminate some or all of our development programs.

**We may face fluctuations in our operating results from period to period, which may result in a decline in our stock price.**

Our operating results have fluctuated significantly from period to period in the past and may rise or fall significantly from period to period in the future as a result of many factors, including:

- the cost of research and development that we engage in;
- a failure to successfully complete preclinical studies and clinical trials in a timely manner or at all, resulting in a delay in receiving, or a failure to receive, the required regulatory approvals to commercialize our drug candidates;
- the timing, receipt and amount of payments, if any, from current and potential future collaborators, including the level of any royalty payments from sales of Erivedge;
- the entry into, or termination of, collaboration agreements;
- the scope, duration and effectiveness of our collaborative arrangements;
- the costs involved in prosecuting, maintaining and enforcing patent claims;
- our ability to operate without infringing upon the proprietary rights of others;
- costs to comply with changes in government regulations;
- costs related to changes in management and reductions or additions of personnel;
- litigation costs;
- costs and accounting charges associated with financing or borrowing arrangements we may enter into from time to time;
- general and industry-specific adverse economic conditions that may affect, among other things, our and our collaborators’ operations and financial results;
- changes in accounting estimates, policies or principles, including changes in revenue recognition policies; and
- the introduction of competitive products and technologies by third parties.

Due to fluctuations in our operating results, quarterly comparisons of our financial results may not necessarily be meaningful, and investors should not rely upon such results as an indication of our future performance. In addition, investors may react adversely if our reported operating results are less favorable than in a prior period or are less favorable than those anticipated by investors or the financial community, which may result in a decline in our stock price.

**Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.**

Our general business strategy and prospects may be adversely affected by the unfavorable economic conditions, volatile business environment and continued unpredictable and unstable market conditions, both domestically and abroad. If equity and credit markets are unfavorable, it may make future debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon research and development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

At December 31, 2011, we had \$37,718,000 of cash, cash equivalents and marketable securities consisting of cash, money market, commercial paper, corporate debt securities, and government obligations. While as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or marketable securities since December 31, 2011, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or marketable securities or our ability to meet our financing objectives. Further dislocations in the credit market may adversely impact the value and liquidity of marketable securities owned by us.

There is a possibility that our stock price may decline due to the volatility of the stock market and the general economic downturn.

**RISKS RELATED TO OUR BUSINESS, INDUSTRY, STRATEGY AND OPERATIONS**

**We and our collaborators may not achieve projected research and development goals in the time frames that we or they announce, which could have an adverse impact on our business and could cause our stock price to decline.**

We set goals for, and make public statements regarding, the timing of certain accomplishments, such as the commencement and completion of preclinical studies, initiation and completion of clinical trials, and other developments and milestones under our proprietary programs and those programs being developed under collaboration agreements. Genentech has also made public statements regarding its expectations for the clinical development and potential filing of additional regulatory submissions for approval of Erivedge, and may in the future make additional statements about its goals and expectations for this collaboration with us. The actual timing of these events can vary dramatically due to a number of factors including without limitation delays or failures in our and our current and potential future collaborators' preclinical studies or clinical trials, the amount of time, effort and resources committed to our programs by us and our current and potential future collaborators and the uncertainties inherent in the regulatory approval process. As a result, we can not assure you that our or our current and potential future collaborators' preclinical studies and clinical trials will advance or be completed in the time frames we or they announce or expect, that we or our current and potential future collaborators will make regulatory submissions or receive regulatory approvals as planned or that we or our current and potential future collaborators will be able to adhere to our current schedule for the achievement of key milestones under any of our internal or collaborative programs. If we or any collaborators fail to achieve one or more of these milestones as planned, our business could be materially adversely affected and the price of our common stock could decline.

**We face substantial competition, which may result in our competitors discovering, developing or commercializing products before or more successfully than we do.**

Our drug candidates face competition from existing and new technologies and products being developed by biotechnology, medical device and pharmaceutical companies, as well as universities and other research institutions. For example, there are several Hedgehog pathway inhibitors presently in clinical development by companies including Bristol-Myers Squibb, Infinity Pharmaceuticals, Millenium Pharmaceuticals, Novartis and Pfizer that may compete with Erivedge. We currently believe that the nearest competitive molecule to Erivedge in clinical development is in Phase II clinical testing in locally advanced and metastatic basal cell carcinoma . We are developing Hedgehog-based therapies under our collaborations with Genentech in the field of cancer. Competitors may discover, characterize and develop Hedgehog pathway inhibitor drug candidates before we do or may compete with us in the same market sector.

In addition, our small molecule network-targeted cancer drug development candidates, which are focused primarily on validated cancer targets, face significant competition from marketed drugs and drugs under development that seek to inhibit the same targets as our drug candidates. We expect competition to intensify in cancer generally and, specifically, in targeted approaches to develop potential cancer therapies as technical advances in the field are made and become more widely known.

Many of our competitors have substantially greater capital resources, research and development staffs and facilities, and more extensive experience than we have. As a result, efforts by other life science, medical device and pharmaceutical companies could render our programs or products uneconomical or result in therapies superior to those that we develop alone or with a collaborator.

For those programs that we have selected for internal development, we face competition from companies that are more experienced in product development and commercialization, obtaining regulatory approvals and product manufacturing. Other smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. As a result, any of these companies may be more successful in obtaining collaboration agreements or other monetary support, approval and commercialization of their products and/or may develop competing products more rapidly and/or at a lower cost. For those programs that are subject to a collaboration agreement, competitors may have greater expertise in discovery, research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and marketing than our collaborators and, consequently, may discover, develop and commercialize products that render our products non-competitive or obsolete.

If we are not able to compete effectively, then we may not be able, either alone or with others, to advance the development and commercialization of our drug candidates, which would adversely affect our ability to grow our business and become profitable.

**The trend towards consolidation in the pharmaceutical and biotechnology industries may adversely affect us.**

There is a trend towards consolidation in the pharmaceutical and biotechnology industries. This consolidation trend may result in the remaining companies in these industries having greater financial resources and technological capabilities, thus intensifying competition in these industries. This trend may also result in fewer potential collaborators or licensees for our therapeutic drug candidates. Also, if a consolidating company is already doing business with our competitors, we may lose existing licensees or collaborators as a result of such consolidation. This trend may adversely affect our ability to enter into agreements for the development and commercialization of our drug candidates, and as a result may harm our business.

**We could be exposed to significant monetary damages and business harm if we are unable to obtain or maintain adequate product liability insurance at acceptable costs or otherwise protect ourselves against potential product liability claims.**

Product liability claims are inherent in the process of researching, developing and commercializing human health care products could expose us to significant liabilities and prevent or interfere with the development or commercialization of our drug candidates. Regardless of their merit or eventual outcome, product liability claims would require us to spend significant time, money and other resources to defend such claims, could result in decreased demand for our future products or result in reputational harm and could result in the payment of a significant damage award.

Although we currently have product liability insurance for our clinical trials, this insurance is subject to deductibles and coverage limitations and may not be adequate in scope to protect us in the event of a successful product liability claim. If any of our drug candidates advance in clinical trials and/or are approved for marketing, we may seek additional insurance coverage. Product liability insurance is expensive and may be difficult to procure. As such, it is possible that we will not be able to obtain product liability insurance on acceptable terms, if at all, or that our product liability insurance coverage will prove to be inadequate to protect us from all potential claims, which may harm our business.

**If we are not able to attract and retain key management and scientific personnel and advisors, we may not successfully develop our drug candidates or achieve our other business objectives.**

We depend upon our senior management, including Daniel R. Passeri, our President and Chief Executive Officer, Maurizio Voi, our Chief Medical and Chief Development Officer, and Michael P. Gray, our Chief Operating Officer and Chief Financial Officer. The loss of the service of any of the key members of our senior management may significantly delay or prevent the achievement of product development and other business objectives. Our officers all serve pursuant to “at will” employment arrangements and can terminate their employment with us at any time. We do not maintain key man life insurance on any of these officers. Replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to research, develop and successfully commercialize products in our areas of core competency.

Our ability to operate successfully will depend on our ability to attract and retain qualified personnel, consultants and advisors. We face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions. We may be unable to attract and retain these individuals, and our failure to do so would have an adverse effect on our business.

**We may seek to acquire complementary businesses and technologies or otherwise seek to expand our operations to grow our business, which may divert management resources and adversely affect our financial condition and operating results.**

We may seek to expand our operations, including without limitation through internal growth and/or the acquisition of businesses and technologies that we believe are a strategic complement to our business model. We may not be able to identify suitable acquisition candidates or expansion strategies and successfully complete such acquisitions or successfully execute any such other expansion strategies. We may never realize the anticipated benefits of any efforts to expand our business. Furthermore, the expansion of our business, either through internal growth or through acquisitions, poses significant risks to our existing operations, financial condition and operating results, including:

- a diversion of management from our existing operations;
- increased operating complexity of our business, requiring greater personnel and resources;
- significant additional cash expenditures to expand our operations and acquire and integrate new businesses and technologies;

- incurrence of debt, other liabilities and contingent liabilities; and
- dilutive stock issuances.

**Any business that we conduct in China will expose us to risks resulting from adverse changes in political, legal and economic policies of the Chinese government, which could impede our preclinical efforts in China and materially and adversely affect the development of our network-targeted cancer programs.**

We currently engage approximately 16 medicinal chemists in China pursuant to a contract research agreement with a medicinal chemistry provider in China. In addition, we have a subsidiary in China, Curis Shanghai, which is currently licensed to conduct business but is not operational.

Conducting business in China exposes us to a variety of risks and uncertainties that are unique to China. The economy of China has been transitioning from a planned economy to a more market-oriented economy. Although in recent years the Chinese government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets and the establishment of sound corporate governance in business enterprises, a substantial portion of productive assets in China is still owned by the Chinese government. In addition, the Chinese government continues to play a significant role in regulating industrial development. It also exercises significant control over China's economic growth through the allocation of resources, controlling payment of foreign currency-denominated obligations, setting monetary policy and providing preferential treatment to particular industries or companies. Efforts by the Chinese government to slow the pace of growth of the Chinese economy could result in interruptions of our development efforts in China. If our research and development efforts in China are delayed due to such interruptions, we may not realize the reductions in costs anticipated from doing business in China. We would also have to consider moving our chemistry and/or biology research that is currently conducted in China to U.S. or European providers, thereby potentially either increasing our overall costs for such services or reducing the total number of chemists and or/ biologists that we could engage.

In addition, the Chinese legal system is a civil law system based on written statutes. Unlike common law systems, it is a system in which decided legal cases have little precedential value. In 1979, the Chinese government began to promulgate a comprehensive system of laws and regulations governing economic matters in general. Accordingly, we cannot predict the effect of future developments in the Chinese legal system, including the promulgation of new laws, changes to existing laws or the interpretation or enforcement thereof, or the preemption of local regulations by national laws. Our business could be materially harmed by any changes in the political, legal or economic climate in China or the inability to enforce applicable Chinese laws and regulations.

**If the estimates we make and the assumptions on which we rely in preparing our financial statements prove inaccurate, our actual results may vary significantly.**

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges taken by us and related disclosure. Such estimates and judgments include the carrying value of our property, equipment and intangible assets, revenue recognition, the value of certain liabilities, including the fair value of our warrant liability, and stock-based compensation expense. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. However, these estimates and judgments, or the assumptions underlying them, may change over time. Accordingly, our actual financial results may vary significantly from the estimates contained in our financial statements.

For a further discussion of the estimates and judgments that we make and the critical accounting policies that affect these estimates and judgments, see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates" elsewhere in this Annual Report on Form 10-K.

**Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.**

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state health-care fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. In addition, during the course of our operations, our directors, executives and employees may have access to material, nonpublic information regarding our business, our results of operations or potential transactions we are considering. Despite our adoption of an Insider Trading Policy, we may not be able to prevent a director, executive or employee from trading in our common stock on the basis of, or while having access to, material, nonpublic information. If a director, executive or employee was to be investigated, or an action was to be brought against a director, executive or employee for insider trading, it could have a negative impact on our reputation and our stock price. Such a claim, with or without merit, could also result in substantial expenditures of time and money, and divert attention of our management team from other tasks important to the success of our business.

## **RISKS RELATING TO OUR INTELLECTUAL PROPERTY**

**We may not be able to obtain patent protection for our technologies and the patent protection we do obtain may not be sufficient to stop our competitors from using similar technology.**

The long-term success of our business depends in significant part on our ability to:

- obtain patents to protect our technologies and discoveries;
- protect trade secrets from disclosure to third-party competitors;
- operate without infringing upon the proprietary rights of others; and
- prevent others from infringing on our proprietary rights.

The patent positions of pharmaceutical and life science companies, including ours, are generally uncertain and involve complex legal, scientific and factual questions. The laws, procedures and standards that the United States Patent and Trademark Office and various foreign intellectual property offices use to grant patents, and the standards that courts use to interpret patents, are not always applied predictably or uniformly and have changed in significant ways and are expected to continue to change. Consequently, the level of protection, if any, that will be obtained and provided by our patents if we attempt to enforce them, and they are challenged, is uncertain.

Patents may not issue from any of the patent applications that we own or license. If patents do issue, the type and extent of patent claims issued to us may not be sufficient to protect our technology from exploitation by our competitors. In addition, issued patents that we own or license may be challenged, invalidated or circumvented. Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States and in many countries abroad are maintained in secrecy until 18 months after filing, it is possible that third parties have filed or maintained patent applications for technology used by us or covered by our pending patent applications without our knowledge. The U.S. Congress recently

passed the Leahy-Smith America Invents Act, or the America Invents Act, which was signed into law in September 2011. The America Invents Act reforms United States patent law in part by changing the standard for patent approval from a “first to invent” standard to a “first to file” standard and developing a post-grant review system. This new legislation changes United States patent law in a way that may weaken our ability to obtain or maintain patent protection for future inventions in the United States.

We may not have rights under patents that may cover one or more of our drug candidates. In some cases, these patents may be owned or controlled by third-party competitors and may prevent or impair our ability to exploit our technology. As a result, we or our current or potential future collaborative partners may be required to obtain licenses under third-party patents to develop and commercialize some of our drug candidates. If we are unable to secure licenses to such patented technology on acceptable terms, we or our collaborative partners may not be able to develop and commercialize the affected drug candidate or candidates.

**We may become involved in expensive and unpredictable patent litigation or other intellectual property proceedings, which could result in liability for damages or require us to cease our development and commercialization efforts.**

There are substantial litigation and other adversarial opposition proceedings regarding patent and other intellectual property rights in the pharmaceutical and life science industries. We may become a party to patent litigation or other proceedings regarding intellectual property rights.

Situations that may give rise to patent litigation or other disputes over the use of our intellectual property include:

- initiation of litigation or other proceedings against third parties to enforce our patent rights, to seek to invalidate the patents held by these third parties or to obtain a judgment that our drug candidates do not infringe the third parties’ patents;
- participation in interference and/or derivation proceedings to determine the priority of invention if our competitors file U.S. patent applications that claim technology also claimed by us;
- initiation of opposition, reexamination, post grant review or inter partes review proceedings by third parties that seek to limit or eliminate the scope of our patent protection;
- initiation of litigation by third parties claiming that our processes or drug candidates or the intended use of our drug candidates infringe their patent or other intellectual property rights; and
- initiation of litigation by us or third parties seeking to enforce contract rights relating to intellectual property that may be important to our business.

The costs associated with any patent litigation or other proceeding, even if resolved favorably, will likely be substantial and a distraction to management. Some of our competitors may be able to sustain the cost of such litigation or other proceedings more effectively than we can because of their substantially greater financial resources. If a patent litigation or other intellectual property proceeding is resolved unfavorably, we or any collaborative partners may be enjoined from manufacturing or selling our future products without a license from the other party and be held liable for significant damages. Moreover, we may not be able to obtain required licenses on commercially acceptable terms or any terms at all. In addition, we could be held liable for lost profits if we are found to have infringed a valid patent, or liable for treble damages if we are found to have willfully infringed a valid patent. Litigation results are highly unpredictable and we or any collaborative partner may not prevail in any patent litigation or other proceeding in which we may become involved. Any changes in, or unexpected interpretations of the patent laws may adversely affect our ability to enforce our patent position. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could damage our ability to compete in the marketplace.

**We face risks relating to the enforcement of our intellectual property rights in China that could adversely affect our business.**

Pursuant to our contract research agreement with a medicinal chemistry provider in China, we currently engage approximately 16 medicinal chemists in China to perform drug discovery research. We seek to protect our intellectual property rights under this arrangement through, among other things, non-disclosure and assignment of invention covenants. Implementation and enforcement of Chinese intellectual property-related laws has historically been inconsistent and damages assessed may fail to reflect the true value of the infringed technology and its market. Accordingly, intellectual property rights and confidentiality protections in China may not be as effective as in the United States or other countries. Policing unauthorized use of proprietary technology is difficult and expensive, and we might need to resort to litigation to enforce or defend patents issued to us or to determine the enforceability, scope and validity of our proprietary rights or those of others. The experience and capabilities of Chinese courts in handling intellectual property litigation varies, and outcomes are unpredictable. Further, such litigation may require significant expenditure of cash and management efforts and could harm our business, financial condition and results of operations. An adverse determination in any such litigation will impair our intellectual property rights and may harm our business, prospects and reputation.

**If we are unable to keep our trade secrets confidential, our technology and proprietary information may be used by others to compete against us.**

We rely significantly upon proprietary technology, information, processes and know-how that are not subject to patent protection. We seek to protect this information through confidentiality and intellectual property license or assignment provisions in agreements with our employees, consultants and other third-party contractors, including our contract research agreement with a medicinal chemistry provider in China, as well as through other security measures. The confidentiality and intellectual property provisions of our agreements and security measures may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors.

**If we fail to comply with our obligations in the agreements under which we license rights to technology from third parties, we could lose license rights that are important to our business.**

We are party to agreements that provide for licenses to us of intellectual property or sharing of rights to intellectual property that is important to our business, and we may enter into additional agreements in the future that provide licenses to us of valuable technology. These licenses impose, and future licenses may impose, various commercialization, milestone and other obligations on us, including the obligation to terminate our use of patented subject matter under certain contingencies. If a licensor becomes entitled to, and exercises, termination rights under a license, we would lose valuable rights and could lose our ability to develop our products. We may need to license other intellectual property to commercialize future products. Our business may suffer if any current or future licenses terminate, if the licensors fail to abide by the terms of the license or fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid or if we are unable to enter into necessary licenses on acceptable terms.

**We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.**

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.



## **RISKS RELATING TO MANUFACTURING AND SALES**

**We will depend on our collaborators and third-party manufacturers to produce most, if not all, of our products under development, and if these third parties do not successfully formulate or manufacture these products, our business will be harmed.**

We have no manufacturing experience or manufacturing capabilities. In order to continue to develop drug candidates, apply for regulatory approvals, and commercialize our products under development, we or any collaborators must be able to manufacture products in adequate clinical and commercial quantities, in compliance with regulatory requirements, including those related to quality control and quality assurance, at acceptable costs and in a timely manner. The manufacture of our drug candidates may be complex, difficult to accomplish and difficult to scale-up when large-scale production is required. Manufacture may be subject to delays, inefficiencies and poor or low yields of quality products. The cost of manufacturing some of our product candidates may make them prohibitively expensive.

To the extent that we or any collaborators seek to enter into manufacturing arrangements with third parties, we and such collaborators will depend upon these third parties to perform their obligations in a timely and effective manner and in accordance with government regulations. Contract manufacturers may breach their manufacturing agreements because of factors beyond our and our collaborators' control or may terminate or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient for us and our collaborators.

Any contract manufacturers with whom we or our collaborators enter into manufacturing arrangements will be subject to ongoing periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with current good manufacturing practices and other governmental regulations and corresponding foreign standards. Any failure by our or our collaborators' contract manufacturers, any collaborators, or us to comply with applicable regulations could result in sanctions being imposed, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of drug candidates, delays, suspension or withdrawal of approvals, seizures or recalls of drug candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. If we or a collaborator need to change manufacturers, the FDA and corresponding foreign regulatory agencies must approve any new manufacturers in advance. This would involve testing and pre-approval inspections to ensure compliance with FDA and foreign regulations and standards.

If third-party manufacturers fail to perform their obligations, our competitive position and ability to generate revenue may be adversely affected in a number of ways, including;

- we and any collaborators may not be able to initiate or continue certain preclinical and/or clinical trials of products that are under development;
- we and any collaborators may be delayed in submitting applications for regulatory approvals for our drug candidates; and
- we and any collaborators may not be able to meet commercial demands for any approved products.

**Because we rely on a limited number of suppliers for the raw materials used in our product candidates, any delay or interruption in the supply of such raw materials could lead to delays in the manufacture and supply of our product candidates.**

We rely on third parties to supply certain raw materials necessary to produce our drug candidates, including CUDC-101, for preclinical studies and clinical trials. There are a small number of suppliers for certain raw materials that we use to manufacture our drug candidates. Such suppliers may not sell these raw materials to us at the times we need them or on commercially reasonable terms, or delivery of these raw materials may be delayed or interrupted. Although we generally do not begin a preclinical study or clinical trial unless we believe we have a sufficient supply of a drug candidate to complete such study or trial, any significant delay in the supply of raw

materials for our drug candidates for an ongoing clinical trial due to the need to replace a third-party supplier could considerably delay completion of certain preclinical studies and/or clinical trials. Moreover, if we were unable to purchase raw materials after regulatory approval had been obtained for our drug candidates, the commercial launch of our drug candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our drug candidates.

**We have no sales or marketing experience and, as such, plan to depend significantly on third parties who may not successfully market and sell any products we develop.**

We have no sales, marketing or product distribution experience. If we receive required regulatory approvals, we plan to rely primarily on sales, marketing and distribution arrangements with third parties, including our collaborative partners. For example, as part of our agreements with Genentech and Debiopharm, we have granted Genentech and Debiopharm the exclusive rights to distribute certain products resulting from such collaborations, if any are ever successfully developed. We may have to enter into additional marketing arrangements in the future and we may not be able to enter into these additional arrangements on terms that are favorable to us, if at all. In addition, we may have limited or no control over the sales, marketing and distribution activities of these third parties and sales through these third parties could be less profitable to us than direct sales. These third parties could sell competing products and may devote insufficient sales efforts to our products. Our future revenues will be materially dependent upon the success of the efforts of these third parties.

We may seek to independently market products that are not already subject to marketing agreements with other parties. If we determine to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

- we may not be able to attract and build a significant and skilled marketing staff or sales force;
- the cost of establishing a marketing staff or sales force may not be justifiable in light of the revenues generated by any particular product; and
- our direct sales and marketing efforts may not be successful.

**Even if we successfully commercialize any products under development, either alone or in collaboration, we face uncertainty with respect to pricing, third-party reimbursement and healthcare reform, all of which could adversely affect the commercial success of our product candidates.**

Our ability to collect significant revenues from sales of our products, if commercialized successfully, may depend on our ability, and the ability of any current or potential future collaboration partners or customers, to obtain adequate levels of coverage and reimbursement for such products from third-party payers such as:

- government health administration authorities;
- private health insurers;
- health maintenance organizations;
- pharmacy benefit management companies; and
- other healthcare-related organizations.

Third party payers are increasingly challenging the prices charged for medical products and services. For example, third-party payers may deny coverage or offer inadequate levels of reimbursement if they determine that a prescribed product has not received appropriate clearances from the FDA, or foreign equivalent, or other government regulators, is not used in accordance with cost-effective treatment methods as determined by the third-party payer, or is experimental, unnecessary or inappropriate. Prices could also be driven down by health maintenance organizations that control or significantly influence purchases of healthcare services and products. If third-party payers deny coverage or offer inadequate levels of reimbursement, we or any collaborators may not be able to market our products effectively or we may be required to offer our products at prices lower than anticipated.

**CURIS, INC.**  
**NOTICE OF ANNUAL MEETING OF STOCKHOLDERS**  
**TO BE HELD MAY 30, 2012**

NOTICE IS HEREBY GIVEN that the annual meeting of stockholders of Curis, Inc. will be held on May 30, 2012 at 10:00 a.m. at the offices of Wilmer Cutler Pickering Hale and Dorr LLP, 60 State Street, Boston, Massachusetts 02109 for the purpose of considering and voting upon the following matters:

1. To elect two Class I directors, each for a term of three years; and
2. To ratify the appointment of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the current fiscal year.

The stockholders will also act on any other business as may properly come before the meeting or any adjournment thereof.

The board of directors has fixed the close of business on April 2, 2012 as the record date for the determination of stockholders entitled to notice of and to vote at the meeting and at any adjournments thereof. Your vote is very important to us. Whether or not you plan to attend the annual meeting in person, your shares should be represented and voted.

In accordance with rules adopted by the Securities and Exchange Commission, we are now furnishing proxy materials to many of our stockholders on the Internet, rather than mailing paper copies of the materials to each stockholder. If you received only a Notice of Internet Availability of Proxy Materials, or Notice, by mail or e-mail, you will not receive a paper copy of the proxy materials unless you request one. Instead, the Notice will provide you with instructions on how to access and view the proxy materials on the Internet. The Notice will also instruct you as to how you may access your proxy card to vote over the Internet or by telephone. If you received a Notice by mail or e-mail and would like to receive a paper copy of our proxy materials, free of charge, please follow the instructions included in the Notice.

The Notice of Internet Availability of Proxy Materials is being mailed to our stockholders on or about April 18, 2012 and sent by e-mail to our stockholders who have opted for such means of delivery on or about April 18, 2012.

Please promptly submit your proxy over the Internet, by phone or by mail. You may revoke your proxy at any time before the 2012 Annual Meeting by following the procedures described in the proxy statement.

All stockholders are cordially invited to attend the meeting.

By Order of the Board of Directors,

/s/ Michael P. Gray

Michael P. Gray, Secretary

Lexington, Massachusetts  
April 18, 2012

**WHETHER OR NOT YOU PLAN TO ATTEND THE MEETING, WE URGE YOU TO VOTE YOUR SHARES OVER THE INTERNET OR BY TELEPHONE, OR TO COMPLETE, DATE, SIGN AND RETURN THE ENCLOSED PROXY CARD IN THE ACCOMPANYING ENVELOPE. NO POSTAGE NEED BE AFFIXED IF THE PROXY CARD IS MAILED IN THE UNITED STATES.**

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**CURIS, INC.**  
**4 Maguire Road**  
**Lexington, Massachusetts 02421**  
**PROXY STATEMENT FOR ANNUAL MEETING OF STOCKHOLDERS**  
***To Be Held on May 30, 2012***

**INFORMATION ABOUT THE ANNUAL MEETING AND VOTING**

This proxy statement is furnished in connection with the solicitation by the board of directors of Curis, Inc. of proxies for use at the annual meeting of stockholders to be held on May 30, 2012 at 10:00 a.m., local time, at the offices of Wilmer Cutler Pickering Hale and Dorr LLP, 60 State Street, Boston, Massachusetts 02109 and at any adjournments thereof. Except where the context otherwise requires, references to “Curis,” “we,” “us,” “our,” and similar terms refer to Curis, Inc. and any of its subsidiaries.

**Important Notice Regarding the Availability of Proxy Materials for  
the Annual Meeting of Stockholders to be Held on May 30, 2012:**

**The proxy statement is available at [www.proxyvote.com](http://www.proxyvote.com).**

**We will, upon written or oral request of any stockholder, furnish copies of our 2011 annual report to stockholders, except for exhibits, without charge. Please address all such requests to us at 4 Maguire Road, Lexington, Massachusetts 02421, Attention: Secretary or telephone: (617) 503-6500.**

In accordance with Securities and Exchange Commission, or SEC, rules, instead of mailing a printed copy of our proxy materials to each stockholder of record, we are furnishing the proxy materials, including this proxy statement, our 2011 annual report and the proxy card for the 2012 annual meeting, to many of our stockholders of record as of the record date via the Internet. We will send the Notice of Internet Availability of Proxy Materials to these stockholders on or about April 18, 2012. The Notice of Internet Availability of Proxy Materials contains instructions for accessing and reviewing our proxy materials as well as instructions for voting your proxy via the Internet. If you prefer to receive printed copies of the proxy materials, you can request printed copies of the proxy materials by Internet, telephone or e-mail. If you choose to receive the print materials by mail, you can either (i) complete, date, sign and return the proxy card, (ii) vote via the Internet in accordance with the instructions on the proxy card or (iii) vote via telephone (toll free) in the United States or Canada in accordance with the instructions on the proxy card. Voting by Internet or telephone must be completed by 11:59 P.M. Eastern Time on May 29, 2012. If you choose not to receive printed copies of the proxy materials, you can vote via the Internet in accordance with the instructions contained in the Notice of Internet Availability of Proxy Materials.

If you received a paper copy of these proxy materials, included with such copy is a proxy card or a voter instruction card for the annual meeting.

**What is the purpose of the annual meeting?**

At the annual meeting, stockholders will consider and vote on the following matters:

1. The election of two Class I directors for a term of three years expiring at the 2015 annual meeting of stockholders;

2. The ratification of the appointment of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the year ending December 31, 2012; and
3. The transaction of other business, if any, that may properly come before the annual meeting or any adjournment of the meeting.

### **Who can vote?**

To be able to vote on the above matters, you must have been a stockholder of record at the close of business on April 2, 2012, the record date for the annual meeting. The number of shares entitled to vote at the meeting is 78,471,459 shares of our common stock, which is the number of shares that were issued and outstanding on the record date.

### **How many votes do I have?**

Each share of our common stock that you owned on the record date entitles you to one vote on each matter that is voted on.

### **Is my vote important?**

Your vote is important regardless of how many shares you own. Please take the time to read the instructions below and vote. Choose the method of voting that is easiest and most convenient for you and please cast your vote as soon as possible.

### **How can I vote?**

**Stockholder of record: Shares registered in your name.** If you are a stockholder of record, that is, your shares are registered in your own name, not in "street name" by a bank or brokerage firm, then you can vote in any one of the following ways:

1. ***You may vote over the Internet.*** If you have Internet access, you may vote your shares from any location in the world at [www.proxyvote.com](http://www.proxyvote.com), by following the instructions on that site or on the "Vote by Internet" instructions on the enclosed proxy card.
2. ***You may vote by telephone.*** You may vote your shares by calling 1-800-690-6903 and following the instructions provided, or following the "Vote by Phone" instructions on the enclosed proxy card.
3. ***You may vote by mail.*** To vote by mail, you need to complete, date and sign the proxy card that accompanies this proxy statement and promptly mail it in the enclosed postage-prepaid envelope. You do not need to put a stamp on the enclosed envelope if you mail it in the United States. The persons named in the proxy card will vote the shares you own in accordance with your instructions on the proxy card you mail. If you return the proxy card, but do not give any instructions on a particular matter described in this proxy statement, the persons named in the proxy card will vote the shares you own in accordance with the recommendations of our board of directors. Our board of directors recommends that you vote FOR proposals 1 and 2.
4. ***You may vote in person.*** If you attend the annual meeting, you may vote by delivering your completed proxy card in person or you may vote by completing a ballot at the meeting. Ballots will be available at the meeting.

**Beneficial owner: Shares held in “street name.”** If the shares you own are held in “street name” by a bank or brokerage firm, then your bank or brokerage firm, as the record holder of your shares, is required to vote your shares according to your instructions. In order to vote your shares, you will need to follow the directions your bank or brokerage firm provides you. Many banks and brokerage firms also offer the option of voting over the Internet or by telephone, instructions for which would be provided by your bank or brokerage firm on your vote instruction form. If you do not give instructions to your bank or brokerage firm, it will still be able to vote your shares with respect to certain “discretionary” items, but will not be allowed to vote your shares with respect to certain “non-discretionary” items. The ratification of the appointment of our independent registered public accounting firm is considered to be a discretionary item on which banks and brokerage firms may vote. The election of directors is considered to be a non-discretionary item on which banks and brokerage firms may not vote, and therefore **if you do not instruct your broker or representative regarding how you would like your shares to be voted, your bank or brokerage firm will not be able to vote on your behalf with respect to the election of directors.** These shares will be treated as “broker non-votes.” “*Broker non-votes*” are shares that are held in “street name” by a bank or brokerage firm that indicates on its proxy that it does not have discretionary authority to vote on a particular matter.

If you wish to come to the meeting to personally vote your shares held in “street name,” you will need to obtain a proxy card from the holder of record (i.e., your brokerage firm or bank).

### **Can I change my vote after I have mailed my proxy card?**

Yes. If you are a stockholder of record, you can change your vote and revoke your proxy at any time before the polls close at the annual meeting by doing any one of the following things:

- signing and returning another proxy card with a later date;
- giving our corporate secretary a written notice before or at the meeting that you want to revoke your proxy; or
- voting in person at the meeting.

Your attendance at the meeting alone will not revoke your proxy.

If you own shares in “street name,” your bank or brokerage firm should provide you with appropriate instructions for changing your vote.

### **What constitutes a quorum?**

In order for business to be conducted at the meeting, a quorum must be present. A quorum consists of the holders of a majority of the shares of common stock issued, outstanding and entitled to vote at the meeting, that is, at least 39,235,730 shares.

Shares of our common stock represented in person or by proxy (including broker non-votes and shares that abstain or do not vote with respect to one or more of the matters to be voted upon) will be counted for the purpose of determining whether a quorum exists.

If a quorum is not present, the meeting will be adjourned until a quorum is obtained.

**What vote is required for each item?**

**Election of Directors (Proposal 1).** The affirmative vote of the holders of a plurality of the votes cast by the stockholders entitled to vote at the meeting is required for the election of directors.

**Ratification of Auditors (Proposal 2).** The affirmative vote of the holders of a majority of the votes cast will be required for the approval of the ratification of the selection of the independent registered public accounting firm.

**How will votes be counted?**

Each share of common stock will be counted as one vote, whether executed by you directly or on a ballot voted in person at the meeting.

Shares that abstain from voting and broker non-votes will not be counted as votes in favor of, or with respect to, any of the proposals and will also not be counted as votes cast. Accordingly, abstentions and broker non-votes will have no effect on the outcome of any of the proposals.

**Who will count the votes?**

Broadridge Financial Solutions, Inc. will count, tabulate and certify the votes.

**How does the board of directors recommend that I vote on the proposals?**

Our board of directors recommends that you vote:

**FOR** the election of two Class I directors for a term of three years expiring at the 2015 annual meeting of stockholders; and

**FOR** the ratification of the appointment of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the 2012 fiscal year.

**Will any other business be conducted at the annual meeting or will other matters be voted on?**

We are not aware of any other business to be conducted or matters to be voted upon at the meeting. If any other matter properly comes before the meeting, the persons named in the proxy card that accompanies this proxy statement will exercise their judgment in deciding how to vote, or otherwise act, at the meeting with respect to that matter or proposal. Our bylaws establish the process for a stockholder to bring a matter before a meeting. See "Stockholder Proposals for 2013 Annual Meeting" on page 44 of this proxy statement.

**Where can I find the voting results?**

We will report the voting results from the annual meeting in a Form 8-K filed with the U.S. Securities and Exchange Commission, or SEC, within four business days following the annual meeting.

**Who bears the costs of soliciting proxies?**

We will bear the costs of soliciting proxies. In addition to solicitations by mail, our directors, officers and regular employees may, without additional remuneration, solicit proxies by telephone, facsimile and personal



interviews. We will also request brokerage houses, custodians, nominees and fiduciaries to forward copies of the proxy material to those persons for whom they hold shares and request instructions for voting the proxies. We will reimburse such brokerage houses and other persons for their reasonable expenses in connection with this distribution.

**How can I obtain a copy of Curis' Annual Report on Form 10-K?**

Our Annual Report on Form 10-K is available in the "Investors" section of our website at [www.curis.com](http://www.curis.com). Alternatively, if you would like us to send you a copy, without charge, please contact:

Curis, Inc.  
4 Maguire Road  
Lexington, MA 02421  
Attention: Secretary  
(617) 503-6500

If you would like us to send you a copy of the exhibits listed on the exhibit index of the Annual Report on Form 10-K, we will do so upon your payment of our reasonable expenses in furnishing a requested exhibit.

**Whom should I contact if I have any questions?**

If you have any questions about the annual meeting or your ownership of our common stock, please contact our secretary at the address or telephone number listed above.

**SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table sets forth certain information, as of December 31, 2011, with respect to the beneficial ownership of shares of our common stock by:

- each person known to us to beneficially own more than 5% of the outstanding shares of common stock,
- each director named in this proxy statement,
- each of the principal executive officer, the principal financial officer, the two other most highly compensated executive officers who were serving as executive officers on December 31, 2011, and one former executive officer who would have been one of the three most highly compensated executive officers but for the fact that he was not serving as an executive officer at the end of the year, whom we refer to collectively as our "named executive officers," and
- all directors and executive officers as a group.

The number of shares of common stock beneficially owned by each person is determined under rules promulgated by the SEC and includes shares over which the indicated beneficial owner exercises voting and/or investment power. Shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days are deemed outstanding for computing the percentage ownership of the person holding the options but are not deemed outstanding for computing the percentage ownership of any other person. For each person named in the table, the number in the "Shares Acquirable Within 60 Days" column consists of shares underlying

stock options or warrants that may be exercised within 60 days after December 31, 2011. Unless otherwise indicated, we believe that each stockholder in the table has sole voting and investment power over the shares listed. The inclusion in the table of any shares does not constitute an admission of beneficial ownership of those shares by the named stockholder. For each person, the "Number of Shares Beneficially Owned" column may include shares of common stock attributable to the person due to that person's voting or investment power or other relationship.

Unless otherwise indicated, the address for each of the stockholders in the table below is c/o Curis, Inc., 4 Maguire Road, Lexington, Massachusetts 02421.

<u>Name and Address of Beneficial Owner</u>	<u>Number of Shares Beneficially Owned (1)</u>	<u>+</u>	<u>Shares Acquirable Within 60 Days</u>	<u>=</u>	<u>Total Number of Shares Beneficially Owned</u>	<u>Percent of Shares Beneficially Owned (2)</u>
<b>5% Stockholders:</b>						
First Eagle Investment Management, LLC (3) .....	17,115,213		245,073		17,360,286	22.4%
BlackRock, Inc. (4) .....	4,724,641		—		4,724,641	6.1%
<b>Directors and Named Executive Officers:</b>						
James R. McNab, Jr. (5) .....	1,453,163		311,666		1,764,829	2.3%
Susan B. Bayh .....	20,000		263,211		283,211	*
Martyn D. Greenacre .....	35,138		404,166		439,304	*
Kenneth I. Kaitin, Ph.D. ....	26,800		169,166		195,966	*
Robert E. Martell, M.D. Ph.D. ....	—		4,166		4,166	*
Marc Rubin, M.D. ....	26,596		38,541		65,137	*
James R. Tobin .....	46,751		229,166		275,917	*
Daniel R. Passeri .....	65,000		2,738,400		2,803,400	3.5%
Michael P. Gray .....	86,613		1,337,843		1,424,456	1.8%
Changgeng Qian, Ph.D., M.D. (6) .....	5,014		1,028,249		1,033,263	1.3%
Mark W. Noel .....	27,540		736,349		763,889	*
Mitchell Keegan, Ph.D (7). ....	—		7,500		7,500	*
<b>All current directors and executive officers as a group (13 persons) .....</b>	<b>1,792,615</b>		<b>7,268,423</b>		<b>9,061,038</b>	<b>10.7%</b>

\* Less than 1% of the outstanding common stock.

- (1) As of December 31, 2011, none of our directors or named executive officers have pledged any of their shares as security.
- (2) The percent of ownership for each stockholder on December 31, 2011 is calculated by dividing (1) the stockholder's Total Beneficial Ownership (i.e., the total number of shares beneficially owned plus the shares acquirable within 60 days) by (2) the sum of 77,117,653 shares of our common stock that were outstanding on December 31, 2011 plus shares of common stock subject to options, warrants or other rights held by such person that will be exercisable within 60 days of December 31, 2011.
- (3) First Eagle Investment Management, LLC ("FEIM") (formerly known as Arnhold and S. Bleichroeder Advisers, LLC), may be deemed to be the beneficial owner of all such shares (assuming exercise of warrants to acquire 245,073 shares), as a result of acting as investment adviser to various clients. 21 April Fund, Ltd., a Cayman Islands company for which FEIM acts as investment adviser, may be deemed to beneficially own 7,445,991 of the 17,360,286 shares (assuming exercise of warrants to acquire 68,250 shares). First Eagle

Value in Biotechnology Master Fund, Ltd., a Cayman Islands company for which FEIM acts as investment adviser, may be deemed to beneficially own 3,837,579 of the 17,360,286 shares (assuming exercise of warrants to acquire 70,073 shares). This information is based on a Schedule 13G/A filed on January 30, 2012 by FEIM. The principal business address of FEIM is 1345 Avenue of the Americas, New York, New York 10105.

- (4) This information is based on a Schedule 13G/A filed on February 13, 2012 by BlackRock, Inc., the parent holding company of BlackRock Institutional Trust Company, N.A., BlackRock Fund Advisors, BlackRock Advisors LLC, and BlackRock Investment Management LLC. The principal business address of BlackRock, Inc. is 40 East 52<sup>nd</sup> Street, New York, New York 10022.
- (5) Includes 1,122,188 shares held directly by Mr. McNab, 130,975 shares held by the McNab Family LLC, and 200,000 shares held by the JR & MW McNab Operating LP.
- (6) Dr. Qian served as our senior vice president of research and preclinical development until February 2012.
- (7) Dr. Keegan served as our vice president of drug development until October 2011.

## PROPOSAL 1—ELECTION OF DIRECTORS

### Directors and Nominees for Directors

Our board of directors is divided into three classes, with one class being elected each year and members of each class holding office for a three-year term. Our board of directors currently consists of two Class I directors, James R. McNab, Jr. and James R. Tobin, three Class II directors, Robert E. Martell, Daniel R. Passeri and Marc Rubin, and three Class III directors, Susan B. Bayh, Martyn D. Greenacre and Kenneth I. Kaitin. The Class I, Class II, and Class III directors will serve until the annual meetings of stockholders to be held in 2012, 2013 and 2014 respectively, and until their respective successors are elected and qualified. At the annual meeting, Class I directors will stand for election.

Our board of directors has nominated Mr. James R. McNab, Jr. and Mr. James R. Tobin as nominees for election as Class I directors, each to serve for three-year terms, until the 2015 annual meeting of stockholders or until their respective successors are elected and qualified. Each of the nominees is currently serving as a director. Both of the nominees have indicated their willingness to serve, if elected; however, if either nominee should be unable to serve, the shares of common stock represented by proxies will be voted for a substitute nominee designated by the board of directors.

Below are the names, ages and certain other information for each member of the board, including the nominees for election as Class I directors. There are no familial relationships among any of our directors, nominees for director and executive officers. In addition to the detailed information presented below for each of our directors, we also believe that each of our directors is qualified to serve on our board and has the integrity, business acumen, knowledge and industry experience, diligence, freedom from conflicts of interest and the ability to act in the interests of our stockholders.

The following table sets forth our directors and their respective ages and positions as of December 31, 2011:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Susan B. Bayh (1)(3)	52	Director
Martyn D. Greenacre (2)(3)	70	Director
Kenneth I. Kaitin, Ph.D. (1)(2)	58	Director
Robert E. Martell, M.D., Ph.D. (4)	48	Director
James R. McNab, Jr. (3)	67	Chairman of the Board
Daniel R. Passeri	51	President and Chief Executive Officer, Director
Marc Rubin, M.D. (2)(4)	56	Director
James R. Tobin (1)	67	Director

- (1) Member of the compensation committee.
- (2) Member of the nominating and corporate governance committee.
- (3) Member of the audit committee.
- (4) Member of the science and technology committee.

**Susan B. Bayh** has served on our board since October 2000. From 1994 to 2001, Ms. Bayh served as the Commissioner of the International Commission between the United States and Canada, overseeing compliance with environmental and water level treaties for the United States-Canadian border. From 1994 to 2004, Ms. Bayh also served as Distinguished Visiting Professor at the College of Business Administration at Butler University.

From 1989 to 1994, Ms. Bayh served as an attorney in the Pharmaceutical Division of Eli Lilly and Company, a pharmaceutical company. Ms. Bayh serves as a director of Dyax Corporation, Dendreon Corporation, Wellpoint, Inc. and Emmis Communications Corporation. Previously, within the past five years, Ms. Bayh served as a director of Nastech Pharmaceutical Company Inc. and MDRNA, Inc. Ms. Bayh received a J.D. from the University of Southern California Law Center and a B.A. from the University of California at Berkeley. We believe that Ms. Bayh's qualifications to serve on our board include her experience in regulatory and compliance matters as well as her considerable experience as a director of other public companies, including companies that are focused on the research and development of cancer therapies.

**Martyn D. Greenacre** has served on our board since February 2000 and was a director of Creative BioMolecules, Inc., a predecessor life science company, from June 1993 to July 2000. Mr. Greenacre has served as Chairman of Life Mist L.L.C., a privately-held company in the field of fire suppression, since September 2001. From June 1997 to June 2001, Mr. Greenacre was Chief Executive Officer of Delsys Pharmaceutical Corporation, a drug formulation company. From 1993 to 1997, Mr. Greenacre was President and Chief Executive Officer of Zynaxis, Inc., a biopharmaceutical company. Mr. Greenacre also serves as a director of Neostem, Inc., Acusphere, Inc., and Formula Pharmaceuticals, a privately-held oncology drug development company. Previously, during the past five years, Mr. Greenacre served as a director of Cephalon, Inc. and Orchestra Therapeutics, Inc., and as a director and Chairman of BMP Sunstone Corporation. Mr. Greenacre received an M.B.A. from Harvard Business School and a B.A. from Harvard College. We believe that Mr. Greenacre's qualifications to serve on our board include his years of experience as President and Chief Executive Officer of various biotech and pharmaceutical companies as well as his experience as a director of other public companies.

**Kenneth I. Kaitin, Ph.D.**, has served on our board since November 2003. Since 1998, Dr. Kaitin has been the Director of the Tufts Center for the Study of Drug Development, an academic drug policy research group providing strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of the drug development process. From 2003 to 2009, Dr. Kaitin was an Associate Professor of Medicine at the Tufts University School of Medicine. Since 2010, Dr. Kaitin has held a primary appointment as Research Professor at the Tufts University School of Medicine, as well as secondary appointments as Professor of Medicine and Professor of Pharmacology and Experimental Therapeutics at Tufts University School of Medicine. Since 1999, he has served on the faculty of the European Center for Pharmaceutical Medicine at the University of Basel, and since 2006 he has been a visiting lecturer at the Tuck School of Business at Dartmouth College. Dr. Kaitin has written extensively on a broad range of drug development issues and has provided public testimony before the U.S. Congress in hearings on pharmaceutical innovation and FDA reform. An internationally recognized expert on the science of drug development, Dr. Kaitin is regularly quoted in the business and trade press on R&D trends in the research-based drug industry and new models of innovation. He is a former Editor-in-Chief of the Drug Information Journal and from 1997 to 1998 he was President of the Drug Information Association. He is currently Editor-in-Chief of *Expert Review of Clinical Pharmacology*, and he serves on the editorial boards of a number of peer-review journals. Dr. Kaitin serves as an expert consultant to the U.S. Department of Defense on Bioterror Countermeasure issues. Dr. Kaitin also serves as a director of Bio-Tree Systems, Inc., a privately-held informatics company, Erevnos Corporation, a privately-held imaging company, Centerphase Solutions, Inc., a privately-held information technology company, and New England Healthcare Institute, a non-profit organization. Previously, within the past five years, Dr. Kaitin served as a director of Phase Forward Inc. Dr. Kaitin received an M.S. and Ph.D. in pharmacology from the University of Rochester and a B.S. from Cornell University. We believe that Dr. Kaitin's qualifications to serve on our board include his expertise in the economics of drug development and biopharmaceutical innovation and his extensive knowledge on a broad range of drug development and life-sciences industry issues.

**Robert E. Martell, M.D., Ph.D.**, has served on our board since September 2011. Since September 2009, Dr. Martell has been employed by the Tufts Medical Center, serving as both the Director of the Neely Center for Clinical Cancer Research, overseeing oncology clinical research, and the Leader of the Cancer Center's Program in Experimental Therapeutics, where he is responsible for developing the center's Phase I oncology clinical development program. Dr. Martell is also an Associate Professor of Medicine at the Tufts University School of Medicine. From 2005 to 2009, Dr. Martell served as Vice President and Chief Medical Officer of MethylGene, a publicly-traded biotechnology company focused on the development of cancer therapeutics. From 2002 to May 2005, Dr. Martell also served as Director of Oncology Global Clinical Research at Bristol-Myers Squibb Company. From 2001 to 2005, Dr. Martell served concurrently as Assistant Clinical Professor of Oncology at Yale University School of Medicine and Staff Physician at the Veterans Affairs hospital. From 2000 to 2002, Dr. Martell worked at Bayer Pharmaceutical Division, where he oversaw the Phase I and Phase II studies. Dr. Martell received a B.A. in chemistry from Kalamazoo College, a Ph.D. in pharmacology from the University of Michigan, and an M.D. from Wayne State University. He completed his internal medicine internship and residency and medical oncology fellowship at Duke University Medical Center, where he was subsequently appointed Assistant Professor, Department of Medicine, Geriatrics and Medical Oncology. We believe that Dr. Martell's qualifications to serve on our board include his expertise in oncology patient care as well as his industry experience in large pharmaceutical and smaller biotechnology companies and that his insights and perspectives are valuable to a small biotechnology company such as Curis.

**James R. McNab, Jr.** has served on our board since February 2000 and has served as Chairman of our board since May 2002. Mr. McNab is a co-founder and served as the chairman of the board of directors of Reprogenesis, Inc., a predecessor life science company, from July 1996 to July 2000. Since 1998, Mr. McNab has served as Chief Executive Officer and Chairman of Palmetto Pharmaceuticals, Inc., formerly eNOS Pharmaceuticals, Inc., a privately-held drug discovery company of which he is a co-founder. In addition, Mr. McNab is a co-founder of other privately-held companies, including Sontra Medical Corporation, a drug delivery company, and Parker Medical Associates, a manufacturer and worldwide supplier of orthopedic and sports-related products. Since January 2009, Mr. McNab has served as executive chairman of FirstString Research, Inc., a privately-held biopharmaceutical company. Mr. McNab received a B.A. in economics from Davidson College and an M.B.A. from the University of North Carolina at Chapel Hill. We believe that Mr. McNab's qualifications to serve on our board include his decades of experience as chairman, founder and/or Chief Executive Officer of various pharmaceutical, medical device and biotechnology companies, including his experience as co-founder of one of our predecessor companies. Mr. McNab has also founded and managed companies in other industries and we believe that his broad range of entrepreneurial creation and oversight is valuable to a small biotechnology company such as Curis.

**Daniel R. Passeri** has served as our President and Chief Executive Officer and as a director since September 2001. From November 2000 to September 2001, Mr. Passeri served as our Senior Vice President, Corporate Development and Strategic Planning. From March 1997 to November 2000, Mr. Passeri was employed by GeneLogic Inc., a biotechnology company, most recently as Senior Vice President, Corporate Development and Strategic Planning. From February 1995 to March 1997, Mr. Passeri was employed by Boehringer Mannheim, a pharmaceutical, biotechnology and diagnostic company, as Director of Technology Management. Mr. Passeri received a J.D. from the National Law Center at George Washington University, an M.Sc. in biotechnology from the Imperial College of Science, Technology and Medicine at the University of London and a B.S. in biology from Northeastern University. We believe that Mr. Passeri's qualifications to serve on our board include his extensive experience in corporate strategy and development, intellectual property strategy and oversight, and technology licensing, as each of these elements are critical to our overall business strategy.

**Marc Rubin, M.D.**, has served on our board since June 2010. Since March 2009, Dr. Rubin has served as Executive Chairman of Titan Pharmaceuticals, Inc., a biopharmaceutical company, and he served as its President and Chief Executive Officer from October 2007 to January 2009. From June 2006 to February 2007, Dr. Rubin served as Head of Global Research and Development for Bayer Schering Pharma AG, a pharmaceutical company, as well as a member of the Executive Committee of Bayer Healthcare, a pharmaceutical and medical products company and subsidiary of Bayer AG, and the Board of Management of Bayer Schering Pharma AG. From October 2003 until the merger of Bayer AG and Schering AG in June 2006, Dr. Rubin was a member of the Executive Board of Schering AG, as well as Chairman of Schering Berlin Inc. and President of Berlex Pharmaceuticals, a division of Schering AG. From 1990 to August 2003, Dr. Rubin held various positions in global clinical and commercial development at GlaxoSmithKline plc, as well as the position of Senior Vice President of Global Clinical Pharmacology & Discovery Medicine from 2001 to 2003. Prior to his pharmaceutical industry career, Dr. Rubin completed subspecialty training and board certification in both medical oncology and infectious diseases at the National Cancer Institute within the National Institutes of Health from 1983 to 1986. From 1986 to 1989, Dr. Rubin also served as an Investigator and on the Senior Staff of the infectious diseases section at the National Cancer Institute. Dr. Rubin also serves as a director of FirstString Research, Inc., Galectin Therapeutics, Surface Logix, Inc. and the Rogosin Institute. Previously, within the past five years, Dr. Rubin served as a director of Medarex, Inc. Dr. Rubin holds an M.D. from Cornell University Medical College. We believe that Dr. Rubin's qualifications to serve on our board include his extensive experience in clinical development as well as his medical, commercial and scientific expertise having held executive-level clinical development positions with Bayer Schering Pharma AG, Schering AG and GlaxoSmithKline plc.

**James R. Tobin** has served on our board since February 2000. From 1995 to July 2000, Mr. Tobin was a member of the board of directors of Creative BioMolecules, Inc., a predecessor life science company. Mr. Tobin is currently retired. From March 1999 to July 2009, Mr. Tobin served as Chief Executive Officer and President of Boston Scientific Corporation, a medical device company. Mr. Tobin was employed by Biogen, Inc. (now Biogen Idec), as President and Chief Executive Officer from February 1997 to December 1998 and President and Chief Operating Officer from February 1994 to February 1997. Prior to joining Biogen, Mr. Tobin was employed by Baxter International Inc., a health care products company, where he served as President and Chief Operating Officer from 1992 to 1994, as Executive Vice President from 1988 to 1992 and in various management positions prior to 1988. Mr. Tobin also serves as a director of Aptus Endosystems and TransMedics. During the past five years, Mr. Tobin served as a director of Boston Scientific Corporation and Applera Corporation. Mr. Tobin received an M.B.A. from Harvard Business School and a B.A. from Harvard College. We believe that Mr. Tobin's qualifications to serve on our board include his decades of experience as President and Chief Executive Officer or Chief Operating Officer of three large biotechnology and medical device companies. In addition, his qualifications include his past experience as a director of Boston Scientific Corporation and one of our predecessor companies, as well as his experience in corporate strategy and organizational expertise.

#### **Board Recommendation**

**OUR BOARD OF DIRECTORS BELIEVES THAT THE ELECTION OF JAMES R. MCNAB, JR. AND JAMES R. TOBIN TO SERVE AS CLASS I DIRECTORS IS IN THE BEST INTERESTS OF CURIS AND OUR STOCKHOLDERS AND, THEREFORE, THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT THE STOCKHOLDERS VOTE "FOR" THE NOMINEES.**

## **CORPORATE GOVERNANCE**

Our board of directors believes that good corporate governance is important to ensure that Curis is managed for the long-term benefit of stockholders. This section describes key corporate governance guidelines and practices that our board of directors has adopted. Complete copies of our corporate governance guidelines, committee charters and code of conduct are available on the Investors – Governance section of our website, [www.curis.com](http://www.curis.com). Alternatively, you can request a copy of any of these documents by writing to our secretary at the following address: Curis, Inc., 4 Maguire Road, Lexington, MA 02421.

### **Corporate Governance Guidelines**

Our board of directors has adopted corporate governance guidelines to assist in the exercise of its duties and responsibilities and to serve the best interests of Curis and our stockholders. These guidelines, which provide a framework for the conduct of the board of directors' business, provide that:

- the board of directors' principal responsibility is to oversee the management of Curis;
- a majority of the members of the board of directors shall be independent directors;
- the independent directors meet regularly in executive session;
- directors have full and free access to management and, as necessary and appropriate, independent advisors;
- all directors are encouraged to participate in continuing director education on an ongoing basis; and
- periodically, the board of directors and its committees will conduct a self-evaluation to determine whether they are functioning effectively.

### **Determination of Independence**

Under applicable Nasdaq rules, a director will only qualify as an "independent director" if, in the opinion of our board, that person does not have a relationship which would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Our board has determined that none of Ms. Bayh, Mr. Greenacre, Dr. Kaitin, Dr. Martell, Mr. McNab, Dr. Rubin or Mr. Tobin has a relationship which would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is an "independent director" as defined under Rule 5605(a)(2) of the Nasdaq Stock Market, Inc. Marketplace Rules.

### **Board Meetings and Attendance**

Our corporate governance guidelines provide that directors are expected to attend the annual meeting of stockholders. All directors attended the 2011 annual meeting of stockholders, except Dr. Joseph M. Davie, a former director who resigned in September 2011, and Dr. Martell, who was elected after the 2011 annual meeting. The board met nine times during the fiscal year ended December 31, 2011, either in person or by teleconference. During the fiscal year ended December 31, 2011, all of our directors attended at least 75% of our board meetings and meetings of the committees on which he or she then served.



## **Board Leadership Structure**

Our board has chosen to separate the role of our chief executive officer and the role of chairman of our board. We believe that this separation is appropriate since our chief executive officer is responsible for the strategic direction of our company, while the chairman of our board is responsible for overseeing the function of the board and for providing guidance to our chief executive officer as needed.

## **Board's Role in Risk Oversight**

The chairman of our board along with the audit committee and the nominating and corporate governance committee are primarily responsible for the oversight of risk and for periodically reporting on such risk oversight to the full board.

## **Board Committees**

Our board has established three standing committees – audit, compensation, and nominating and corporate governance – each of which operates under a charter that has been approved by our board. Current copies of each committee's charter are posted on our website, [www.curis.com](http://www.curis.com).

Our board has determined that all of the members of each of the board of directors' three standing committees are independent as defined under the rules of the Nasdaq Stock Market, including, in the case of all members of the audit committee, the independence requirements contemplated by Rule 10A-3 under the Exchange Act.

Our board has also established a science and technology committee which operates under a charter that has been approved by our board. A current copy of the committee charter is posted on our website.

### *Audit Committee*

The audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- pre-approving all audit and non-audit services of our independent registered public accounting firm, except for de minimis non-audit services which are approved in accordance with applicable SEC rules, including meeting with our independent registered public accounting firm prior to the annual audit to discuss the planning and staffing of the audit;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of certain reports from such firm;
- reviewing and discussing with management and the independent registered public accounting firm our annual and quarterly financial statements and related disclosures, earnings releases and other publicly disseminated financial information;
- reviewing and discussing with our independent registered public accounting firm matters concerning the quality, not just the acceptability, of our accounting determinations, particularly with respect to judgmental areas;

- monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- discussing our risk management policies;
- establishing policies regarding hiring employees from the independent auditor and procedures for the receipt and retention of accounting-related complaints and concerns;
- meeting independently with our independent registered public accounting firm and management on a quarterly basis;
- reviewing and approving or ratifying any related person transactions;
- establishing, and periodically reviewing, complaint procedures for (i) the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or auditing matters; and (ii) the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters; and
- preparing the audit committee report required by SEC rules, which is included on page 19 of this proxy statement.

The members of the audit committee are Ms. Bayh, Mr. Greenacre (Chair) and Mr. McNab. The audit committee met seven times during the fiscal year ended December 31, 2011. The board of directors has determined that Mr. Greenacre is an “audit committee financial expert” as defined by applicable SEC rules.

#### *Compensation Committee*

The compensation committee’s responsibilities include:

- determining the chief executive officer’s compensation;
- reviewing and approving, or making recommendations to the board with respect to, the compensation of our other executive officers;
- overseeing an evaluation of our senior executives;
- overseeing and administering our cash and equity incentive plans;
- reviewing and making recommendations to the board with respect to director compensation;
- reviewing and discussing annually with management our “Compensation Discussion and Analysis,” which is included beginning on page 21 of this proxy statement;
- preparing the compensation committee report required by SEC rules, which is included on page 43 of this proxy statement; and
- reviewing and making recommendations to the board with respect to management succession planning.

The processes and procedures followed by our compensation committee in considering and determining executive and director compensation are described below under the heading “Executive and Director Compensation Processes.”

The members of the compensation committee are Ms. Bayh, Dr. Kaitin and Mr. Tobin (Chair). The compensation committee met six times during the fiscal year ended December 31, 2011.

#### *Nominating and Corporate Governance Committee*

The nominating and corporate governance committee's responsibilities include:

- identifying individuals qualified to become board members;
- recommending to the board the persons to be nominated for election as directors and to each of the board's committees; and
- overseeing an annual evaluation of the board.

The processes and procedures followed by the nominating and corporate governance committee in identifying and evaluating director candidates are described below under the heading "Director Nomination Process."

The current members of the nominating and corporate governance committee are Dr. Kaitin (Chair), Mr. Greenacre and Dr. Rubin. The nominating and corporate governance committee met three times during the fiscal year ended December 31, 2011.

#### *Science and Technology Committee*

The science and technology committee's responsibilities include:

- reviewing, evaluating, and advising the board and management regarding the long-term strategic goals and objectives and the quality and direction of the company's research and development programs;
- monitoring and evaluating trends in research and development, and recommending to the board and management emerging technologies for building the company's technological strength;
- recommending approaches to acquiring and maintaining technology positions;
- advising the board and management on the scientific aspects of business development;
- regularly reviewing the company's research and development pipeline;
- assisting the Board with its oversight responsibility for enterprise risk management in areas affecting the company's research and development; and
- reviewing such other topics as delegated to the committee from time to time.

The current members of the science and technology committee are Dr. Rubin and Dr. Martell.

#### **Executive and Director Compensation Processes**

The compensation committee oversees our compensation programs. In this capacity, the compensation committee determines and approves all compensation decisions related to our executive officers. In addition, the compensation committee periodically reviews and makes recommendations to the board with respect to director compensation. With respect to the grant of equity compensation awards and the grant of cash awards, if any, structured under our stock incentive plan as performance-based compensation that is exempt from Section 162(m) of the Internal Revenue Code of 1986, as amended, the compensation committee may form, and delegate authority to, one or more subcommittees as it deems appropriate from time to time under the circumstances (including (a) a subcommittee consisting of a single member and (b) a subcommittee consisting of

at least two members, each of whom qualifies as a “non-employee director,” as such term is defined from time to time in Rule 16b-3 promulgated under the Exchange Act, and an “outside director,” as such term is defined from time to time in Section 162(m) of the Internal Revenue Code of 1986, as amended). The compensation committee did not form or delegate authority to any subcommittees during the fiscal year ending December 31, 2011.

The compensation committee has the authority to retain and terminate any compensation consultant to be used to assist in the evaluation of executive officer compensation and has the sole authority to approve the consultant’s fees and other retention terms. The compensation committee also has authority to commission compensation surveys or studies as the need arises. Periodically, the compensation committee retains an independent third party compensation consultant to review director and officer compensation. The compensation committee last engaged a compensation consultant during fiscal year 2010 to review director and officer compensation.

Compensation committee meetings typically have included, for all or a portion of each meeting, our chief financial officer and, for meetings in which executive officer compensation decisions are made, the chairman of our board and our chief executive officer. The compensation committee typically seeks the chairman’s input in compensation matters involving our chief executive officer. The chief executive officer provides input on all other executive officer compensation matters including the appropriate mix of compensation for such other officers. The chief executive officer and the chief financial officer do not attend the portion of any meeting during which any decisions regarding their respective compensation are made.

### **Risks Arising from Compensation Policies and Practices**

Employee compensation generally consists of salary, stock option awards and, depending on overall company performance among other things, discretionary cash bonus payments. We have reviewed our compensation policies and practices for all employees and have concluded that any risks arising from our policies and programs are not reasonably likely to have a material adverse effect on our company.

### **Director Nomination Process**

The process followed by the nominating and corporate governance committee to identify and evaluate director candidates includes requests to board members and others for recommendations, meetings from time to time to evaluate biographical information and background material relating to potential candidates, and interviews of selected candidates by members of the nominating and corporate governance committee and the board.

In considering whether to recommend any particular candidate for inclusion in the board’s slate of recommended director nominees, the nominating and corporate governance committee will apply the criteria set forth in its charter. These criteria include the candidate’s integrity, business acumen, knowledge of our business and industry, experience, diligence, freedom from conflicts of interest and the ability to act in the interests of all stockholders. Our nominating and corporate governance charter provides that the value of diversity on our board should be considered by the nominating and corporate governance committee. The committee does not assign specific weights to particular criteria and no particular criterion is a prerequisite for each prospective nominee. We believe that the backgrounds and qualifications of our directors, considered as a group, should provide a composite mix of experience, knowledge and abilities that will allow the board to fulfill its responsibilities. We do not discriminate against candidates based on their race, religion, national origin, sex, sexual orientation, disability or any other basis proscribed by law.

Stockholders may recommend individuals to the nominating and corporate governance committee for consideration as potential director candidates by submitting candidate names, together with appropriate biographical information and background materials and a statement as to whether the stockholder or group of stockholders making the recommendation has beneficially owned more than 5% of our common stock for at least a year as of the date such recommendation is made, to the Nominating and Corporate Governance Committee, c/o Secretary, Curis, Inc., 4 Maguire Road, Lexington, MA 02421. Assuming that appropriate biographical and background material has been provided on a timely basis, the committee will evaluate stockholder-recommended candidates by following substantially the same process, and applying substantially the same criteria, as it follows for candidates submitted by others. If the board determines to nominate a stockholder-recommended candidate and recommends his or her election, then his or her name will be included in our proxy card for the next annual meeting.

Stockholders also have the right under our bylaws to directly nominate director candidates, without any action or recommendation on the part of the committee or the board of directors, by following the procedures set forth under “Stockholder Proposals for 2013 Annual Meeting.”

### **Communicating with the Independent Directors**

The board will give appropriate attention to written communications that are submitted by stockholders, and will respond if and as appropriate. The chairman of the board of directors is primarily responsible for monitoring communications from stockholders and for providing copies or summaries to the other directors as he or she considers appropriate.

Communications are forwarded to all directors if they relate to important substantive matters and include suggestions or comments that the chairman of the board considers to be important for the directors to know. In general, communications relating to corporate governance and corporate strategy are more likely to be forwarded than communications relating to ordinary business affairs, personal grievances and matters as to which we receive repetitive or duplicative communications.

Stockholders who wish to send communications on any topic to the board should address such communications to the Chairman of the Board of Directors, c/o Secretary, Curis, Inc., at 4 Maguire Road, Lexington, MA 02421.

### **Code of Business Conduct and Ethics**

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer. We have posted a current copy of the code on our website, [www.curis.com](http://www.curis.com). In addition, we intend to post on our website all disclosures that are required by law or NASDAQ stock market listing standards concerning any amendments to, or waivers of, any provision of the code. We have not had any waivers of any provision of this code as of the date of this proxy statement.

### **Policies and Procedures for Related Person Transactions**

Our board has adopted written policies and procedures for the review of any transaction, arrangement or relationship in which Curis is a participant, the amount involved exceeds \$120,000, and one of our executive officers, directors, director nominees or 5% stockholders (or their immediate family members), each of whom we refer to as a “related person,” has a direct or indirect material interest.

If a related person proposes to enter into such a transaction, arrangement or relationship, which we refer to as a “related person transaction,” the related person must report the proposed related person transaction to our chief financial officer and/or general counsel. The policy calls for the proposed related person transaction to be reviewed and, if deemed appropriate, approved by the board’s audit committee. Whenever practicable, the reporting, review and approval will occur prior to entry into the transaction. If advance review and approval is not practicable, the audit committee will review, and, in its discretion, may ratify the related person transaction at the next meeting of the committee. The policy also permits the chairman of the audit committee to review and, if deemed appropriate, approve proposed related person transactions that arise between committee meetings, subject to ratification by the audit committee at its next meeting. Any related person transactions that are ongoing in nature will be reviewed annually. The audit committee will review and consider such information regarding the related person transaction as it deems appropriate under the circumstances.

The audit committee may approve or ratify the transaction only if the committee determines that, under all of the circumstances, the transaction is not inconsistent with Curis’ best interests. The audit committee may impose any conditions on the related person transaction that it deems appropriate.

In addition to the transactions that are excluded by the instructions to the SEC’s related person transaction disclosure rule, the board has determined that the following transactions do not create a material direct or indirect interest on behalf of related persons and, therefore, are not related person transactions for purposes of this policy:

- interests arising solely from the related person’s position as an executive officer of another entity (whether or not the person is also a director of such entity), that is a participant in the transaction, where (a) the related person and all other related persons own in the aggregate less than a 10% equity interest in such entity, and (b) the related person and his or her immediate family members are not involved in the negotiation of the terms of the transaction and do not receive any special benefits as a result of the transaction; and
- a transaction that is specifically contemplated by provisions of our charter or bylaws.

The policy provides that transactions involving compensation of executive officers shall be reviewed and approved by the compensation committee in the manner specified in its charter.

### **Related Person Transactions**

We are party to a Drug Development Partnership and License Agreement for CUDC-906 and CUDC-908 (the “License Agreement”), effective as of February 24, 2012, with Guangzhou BeBetter Medicine Technology Company Ltd., a company organized under the laws of the People’s Republic of China (“GBMT”). Dr. Changgeng Qian, our former Senior Vice President, Discovery and Preclinical Development, is the founder, owner, and legal representative of GBMT. Under the terms of the License Agreement, we granted to GBMT an exclusive royalty-free license, with the right to grant sublicenses subject to certain conditions, to develop, manufacture, market and sell any product containing CUDC-906 or CUDC-908 in the GBMT Territory (China, Macau, Taiwan and Hong Kong). In addition, we granted to GBMT a non-exclusive, royalty-free manufacturing license, with the right to grant sublicenses subject to certain conditions, to manufacture CUDC-906 or CUDC-908 or any product containing CUDC-906 or CUDC-908 outside of the GBMT Territory solely to import the compounds or products into the GBMT Territory. We have agreed to pay up to \$400,000 under the License Agreement for certain IND-enabling activities, of which none has been paid to date.

## **Audit Committee Report**

The audit committee has reviewed our audited financial statements for the fiscal year ended December 31, 2011, and has discussed these financial statements with our management and our independent registered public accounting firm.

Our management is responsible for the preparation of our financial statements and for maintaining an adequate system of disclosure controls and procedures and internal control over financial reporting for that purpose. Our independent registered public accounting firm is responsible for conducting an independent audit of our annual financial statements in accordance with the standards of the Public Company Accounting Oversight Board and issuing a report on the results of their audit. The audit committee is responsible for providing independent, objective oversight of these processes.

The audit committee has also received from, and discussed with, our independent registered public accounting firm various communications that our independent registered public accounting firm is required to provide to the audit committee, including the matters required to be discussed by the Statement on Auditing Standards No. 61, as amended (AICPA, Professional Standards, Vol. 1, AU section 380), as adopted by the Public Company Accounting Oversight Board in Rule 3200T. SAS 61, as amended, requires our independent registered public accounting firm to discuss with the audit committee, among other things, the following:

- methods to account for significant unusual transactions;
- the effect of significant accounting policies in controversial or emerging areas for which there is a lack of authoritative guidance or consensus;
- the process used by management in formulating particularly sensitive accounting estimates and the basis for the auditors' conclusions regarding the reasonableness of those estimates; and
- disagreements with management over the application of accounting principles, the basis for management's accounting estimates and the disclosures in the financial statements.

The audit committee has received the written disclosures and the letter from our independent registered public accounting firm required by applicable requirements of the Public Company Accounting Oversight Board regarding our independent registered public accounting firm's communications with the audit committee concerning independence, and has discussed with the independent registered public accounting firm their independence from Curis.

Based on the review and discussions referred to above, the audit committee recommended to our board of directors that the audited financial statements be included in our Annual Report on Form 10-K for the year ended December 31, 2011.

Submitted by the audit committee of our board of directors.

Martyn D. Greenacre (Chair)  
Susan B. Bayh  
James R. McNab, Jr.

## Independent Registered Public Accounting Firm's Fees and Other Matters

### *Independent Registered Public Accounting Firm's Fees*

The following table summarizes the fees of PricewaterhouseCoopers LLP, our independent registered public accounting firm, billed to us for each of the last two fiscal years:

<u>Fee Category</u>	<u>2011</u>	<u>2010</u>
Audit Fees (1) .....	\$315,000	\$305,000
Audit-related fees (2) .....	56,500	35,000
All Other Fees (3) .....	1,800	1,500
Total Fees .....	<u>\$373,300</u>	<u>\$341,500</u>

- (1) Audit fees consist of fees for the audit of our financial statements, the audit of our internal control over financial reporting, the review of the interim financial statements included in our quarterly reports on Form 10-Q, and other professional services provided in connection with statutory and regulatory filings or engagements. 100% of the audit fees for 2011 and 2010 were pre-approved by the audit committee. These amounts exclude reimbursement of out of pocket expenses of \$3,250 for each of 2011 and 2010.
- (2) Audit-related fees for 2011 consist of fees associated with a comfort letter for our at-the-market sales agreement entered into in July 2011. Audit-related fees for 2010 consist of fees associated with our registered direct offering which was initiated in December 2009, including a comfort letter. In addition, in 2010 we incurred fees associated with various registration statement filings. 100% of the audit-related fees for 2011 and 2010 were pre-approved by the audit committee.
- (3) Other fees consist of an annual license fee for use of Comperio, accounting research software. None of the other fees incurred during 2011 and 2010 were for services provided under the de minimis exception to the audit committee pre-approval requirements. 100% of these fees for 2011 and 2010 were pre-approved by the audit committee.

### *Pre-Approval Policy and Procedures*

Our audit committee has adopted policies and procedures relating to the approval of all audit and non-audit services that are to be performed by our independent registered public accounting firm. This policy generally provides that we will not engage our independent registered public accounting firm to render audit or non-audit services unless the audit committee specifically approves the service in advance or the engagement is entered into pursuant to one of the pre-approval procedures described below.

From time to time, our audit committee may pre-approve specified types of services that are expected to be provided to us by our independent registered public accounting firm during the next 12 months. Any such pre-approval is detailed as to the particular service or type of services to be provided and is also generally subject to a maximum dollar amount.

The audit committee has also delegated to the chairman of the audit committee the authority to approve any audit or non-audit services to be provided to us by our independent registered public accounting firm. Any approval of services by a member of the audit committee pursuant to this delegated authority is reported on at the next meeting of the audit committee.



## EXECUTIVE AND DIRECTOR COMPENSATION AND RELATED MATTERS

### Compensation Discussion and Analysis

This Compensation Discussion and Analysis describes our compensation strategy, policies, programs and practices for our executive officers identified in the “Summary Compensation Table.” Our executive officers consist of our chief executive officer, our chief financial officer, the two other most highly compensated executive officers who were serving as executive officers on December 31, 2011, and one former executive officer who would have been one of the three most highly compensated executive officers but for the fact that he was not serving as an executive officer at the end of the year, whom we refer to collectively as our “named executive officers.” In this Compensation Discussion and Analysis and the discussion that follows, we include information with respect to Dr. Qian, our former senior vice president of research and preclinical development, who ceased to serve as an officer in February 2012, and Dr. Mitchell Keegan, our former vice president of drug development, who ceased to serve as an officer in October 2011. Information concerning compensation paid to Dr. Qian and Dr. Keegan is included in accordance with the requirements of the SEC’s proxy disclosure rules. Compensation decisions for our executive officers are made by the compensation committee of our board of directors.

At our June 2011 annual meeting, we held our first “say-on-pay” advisory stockholder vote on the compensation of our named executive officers. The compensation committee noted that our proposal regarding the say-on-pay vote was supported among our stockholders. For our fiscal year 2011 and 2012 executive compensation programs, no specific component of the program was altered based on the results of the say-on-pay vote. Our compensation committee and our board of directors believe that our executive compensation has been appropriately tailored to our business strategies, aligns pay with performance, and reflects best practices regarding executive compensation. The committee will continue to consider stockholder sentiments about our core principles and objectives when determining executive compensation.

### Executive Summary

The compensation paid to our named executive officers in 2011 reflected our primary objectives of attracting and retaining key executive officers critical to our long-term success, recognizing and rewarding overall company performance and each executive officer’s individual performance and level of responsibility, as well as continuing to align our executive officers’ incentives with stockholders’ interests.

### *2011 Corporate Results*

We and our collaborators achieved a number of our key corporate goals and objectives in 2011 including:

- FDA approval by our collaborator Genentech, a member of the Roche Group, of Erivedge™ (vismodegib) capsule, a hedgehog pathway inhibitor for the treatment of adults with a type of skin cancer, called basal cell carcinoma, that has spread to other parts of the body or that has come back after surgery or that their healthcare provider decides cannot be treated with surgery or radiation and the filing by Roche of a marketing authorization application for Erivedge with the European Medicines Agency, resulting in an aggregate of \$24 million in milestone payments to Curis in 2011;
- the completion of our phase I expansion study of CUDC-101, our HDAC, EGFR and Her2 inhibitor, in breast, gastric, head and neck, liver and non-small cell lung cancer patients;

- the initiation of a phase I dose escalation study of CUDC-101 in combination with standard-of-care cisplatin and radiation in human papillomavirus negative locally advanced head and neck cancer patients;
- the advancement of a preclinical oral formulation of CUDC-101 towards planned phase I clinical testing in 2012;
- the selection of CUDC-907, our HDAC and PI3K inhibitor, as a development candidate, and advancement of this molecule towards planned phase I clinical testing in 2012;
- the entry into an agreement with The Leukemia & Lymphoma Society, or LLS, under which LLS will fund approximately 50% of our direct costs associated with the early stage clinical development of CUDC-907 if we succeed in advancing this development candidate into a clinical trial for patients with B-cell lymphoma and multiple myeloma;
- continued progress in our research and development activities on our other preclinical proprietary targeted cancer programs;
- the completion by our licensee Debiopharm of phase I clinical testing of heat shock protein 90, or Hsp90, compound Debio 0932;
- the expansion of our clinical development capabilities, highlighted by our hiring in November 2011 of Maurizio Voi, M.D. as our Chief Medical and Chief Development Officer, who brings us approximately 25 years of cancer drug development experience, including senior positions at Pfizer, Bristol Myers-Squibb and Eli Lilly and Company; and
- meeting planned objectives within our 2011 operating budget.

#### *Pay-for-Performance*

In 2011, the compensation committee adhered to its long-standing pay-for-performance philosophy. As such, a significant portion of total 2011 executive compensation was comprised of cash incentives and long-term compensation based on corporate performance. The average of our executive officers' base salary comprised 52% of total executive officer compensation.

Key compensation decisions for 2011 were as follows:

- Our compensation committee did not change the base salaries for our executive officers from base salaries that were set in February 2010.
- In January 2011, the compensation committee approved the payment of a discretionary one-time bonus to our executive officers of an aggregate of \$158,334 in recognition of the achievement of key 2010 operating goals. These discretionary bonuses ranged between 7% and 14% of the respective executive officer's 2010 base salary.
- In January 2011, the compensation committee approved a cash incentive award program for our executive officers pursuant to which each of the named executive officers was entitled to receive a cash incentive award that is contingent upon the compensation committee's determination that we had achieved specified capital raising transaction objectives for the fiscal year ended December 31, 2011. Specifically, the program provides that each executive officer who is serving as an executive officer on the date the award is paid will be entitled to receive a cash incentive award based upon the company

having actually received or having earned the unconditional right to receive, at any point on or after January 1, 2011 and on or before December 31, 2011, \$20.0 million of additional working capital such as in the form of unrestricted cash payments through milestones, license fees or other payments under existing or new collaborations and/or through the sale of equity to one or more third parties, provided that such equity sale is at a fair market value that exceeds the fair market value of the common stock as of January 7, 2011. The compensation committee retained the authority and discretion to amend, modify, alter or terminate the cash incentive program at any time based upon such factors as the compensation committee deemed appropriate. In January 2012, the compensation committee determined that it would award cash incentive payments to executive officers at 100% of target levels based upon the company's performance during the year, notwithstanding that the company did not fully meet the prescribed target for capital raising, resulting in cash incentive awards to Messrs. Passeri, Gray and Noel and Dr. Qian at a total costs of \$425,000.

- In January 2011, the compensation committee granted stock options to our executive officers that had an expected value on a Black-Scholes basis that was between the 50<sup>th</sup> and 75<sup>th</sup> percentiles of the then-applicable peer group. The purpose of these equity grants was to create an incentive for our executive officers to increase stockholder value over time through stock price growth, thereby aligning our executives' interests with those of our stockholders.

In 2011, our compensation committee also considered whether or not to implement stock ownership guidelines for our executive officers and directors. Based upon the fact that the current stock ownership of our officers and directors is aligned with prevalent practice, the compensation committee determined that it would continue to monitor the adoption of ownership policies among Curis' peer group and the broader pre-commercial life sciences sector and would not recommend the implementation of stock ownership guidelines at this time.

### **Our Compensation Program**

The primary objectives of the compensation committee with respect to executive officer compensation are to:

- attract and retain key executive officers critical to our long-term success;
- recognize and reward overall company performance and each executive officer's individual performance and level of responsibility; and
- align our executive officers' incentive compensation with stockholder interests.

To achieve these objectives, the compensation committee has previously set base salary and total cash compensation at approximately the 50<sup>th</sup> percentile and long-term incentive compensation at the 75<sup>th</sup> percentile of peer company benchmarking data. In September 2010, our compensation committee retained Towers Watson to serve as an independent outside consultant reporting directly to the compensation committee with respect to executive and director compensation and stock ownership guidelines. Towers Watson was engaged to, among other things, conduct a benchmarking assessment of our executive officer compensation. Our compensation committee did not retain Towers Watson in 2011, since the compensation committee believed that peer group compensation levels were unlikely to have changed materially since December 2010. The compensation committee historically has engaged Towers Watson every other year and intends to retain Towers Watson in 2012 to conduct an independent review of executive officer and director compensation. The results of the 2010 benchmarking assessment were presented to our compensation committee and were utilized by our compensation

committee in setting 2011 compensation for our executive officers and were also taken into consideration by the compensation committee in setting 2012 compensation for our executive officers. The benchmarking was based upon:

- comparative compensation data for 14 companies in our industry that were recommended by Towers Watson and adopted by the compensation committee as appropriate peer companies based upon each company's financial profile, state of development and oncology focus; and
- a review of executive officer compensation data for companies in the 2010 Radford Global Life Sciences Compensation Survey with a headcount of less than 50 employees.

The peer group companies were as follows:

Antigenics, Inc.	Keryx Biopharmaceuticals, Inc.
Arqule, Inc.	Oxigene, Inc.
AVEO Pharmaceuticals, Inc.	Pharmacyclics Inc.
Celldex, Inc.	Sunesis Pharmaceuticals, Inc.
Idera Pharmaceuticals, Inc.	Telik, Inc.
Immunomedics, Inc.	Threshold Pharmaceuticals, Inc.
Infinity Pharmaceuticals, Inc.	ZIOPHARM Oncology, Inc.

The elements of compensation included in the benchmarking assessment consisted of base salary, short-term annual incentive compensation opportunities, total cash compensation, the fair value of long-term incentive awards and actual total direct compensation for each of our executive officers as compared to the peer group companies. Towers Watson conducted a competitive analysis of compensation at the 25<sup>th</sup>, 50<sup>th</sup> and 75<sup>th</sup> percentiles of the benchmarking data. The benchmarking assessment showed that our executive officers' 2011 base salary levels were generally at or below the 50<sup>th</sup> percentile of our peer group companies, but that total 2011 cash compensation paid to our executive officers, which includes short-term incentive awards, were generally at or above the 50<sup>th</sup> percentile. Long-term incentive compensation approximated the 50<sup>th</sup> percentile but was well below the 75<sup>th</sup> percentile of the peer group companies.

Other than pursuant to its September 2010 engagement, Towers Watson does not currently provide any other services to our compensation committee or to us.

In determining executive officer compensation, the compensation committee also considers the overall performance and financial condition of the company and each individual executive officer's performance in contributing to company performance. The compensation committee also considers its desire to retain adequate shares available for future grant in our 2010 stock incentive plan when determining the size of stock awards to its executive officers. The company's corporate goals and objectives are established through a process that involves input by our board and executive officers, including our chief executive officer. Management reports on progress towards the achievement of these goals as part of our periodic board of directors meetings. The compensation committee believes that aligning executive compensation with the successful achievement of these goals has the potential to create long-term value for our stockholders.

Our chief executive officer evaluates the performance of each of the other executive officers at least once annually against established company goals and objectives for such executive officer and also takes into consideration each executive officer's contribution to the achievement of company goals and objectives. These annual assessments are provided either orally or through a written periodic review. The chief executive officer

provides recommendations to the compensation committee for all elements of compensation of our other executive officers based upon these evaluations, and the compensation committee considers our chief executive officer's assessments when determining compensation for our executive officers other than our chief executive officer. The compensation committee evaluates the performance of the chief executive officer based upon its assessment of the chief executive officer's performance, and this assessment is updated at periodic meetings as well as through recommendations from the chairman of our board of directors. Our chief executive officer does not participate in the determination of his own compensation.

For a further discussion of the processes and procedures used by our compensation committee in considering and determining executive and director compensation, see "Executive and Director Compensation Processes" beginning on page 15 of this proxy statement.

### **Elements of Compensation and Analysis of 2011 Payments**

The elements of executive officer compensation vary from year to year and generally consist of the following:

- base salary;
- discretionary annual bonuses;
- short-term cash incentives;
- stock option and restricted stock awards;
- insurance, retirement and other employee benefits; and
- change in control and severance benefits.

We do not have any formal or informal policy or target for allocating compensation between long-term and short-term compensation, between cash and non-cash compensation or among the different forms of non-cash compensation. The compensation committee, after considering information including company performance, individual executive officer performance, the financial condition of the company, benchmarking data and other market compensation for executive officers at other similarly-sized oncology-focused companies, determines what it believes to be the appropriate level and mix of the various compensation components.

#### *Base Salary*

Base salary is used to recognize the experience, skills, knowledge and responsibilities required of all our employees, including our executives. Base salaries for our executive officers are established based on the scope of their responsibilities, periodically taking into account competitive market compensation paid by other companies for similar positions as well as the financial condition of the company. Base salaries are reviewed annually, and adjusted from time to time to reflect promotions and to realign salaries with market levels after taking into account individual responsibilities, performance and experience as well as the financial health of the company. The compensation committee generally believes that executive officer base salaries should approximate the 50<sup>th</sup> percentile of the range of salaries for executive officers in similar positions with similar responsibilities at comparable companies.

Our compensation committee set the base salaries for our executive officers in 2011 at the same levels as 2010. The base salaries for our executive officers for 2011 were: (i) Mr. Passeri, \$400,000; (ii) Mr. Gray, \$300,000; (iii) Dr. Keegan, \$250,000; (iv) Mr. Noel, \$215,000; and (v) Dr. Qian, \$275,000.

Previously, in February 2010, base salary adjustments for Mr. Passeri and Mr. Gray were made to bring their salaries back to their respective levels prior to October 2008 salary reductions when our compensation committee reduced the base salaries for our executive officers as part of our efforts to conserve our cash resources and in reaction to unfavorable general economic and capital market conditions existing at the time. The compensation committee also granted stock awards in 2008 in order to offset the concomitant decrease in base compensation for each executive officer. Mr. Noel's base salary increased \$5,000, or 2.4%, above the October 2008 level. Dr. Qian's base salary increased \$25,000, or 10%, above the October 2008 level primarily based on his promotion to senior vice president, discovery and preclinical development.

The base salary amounts for our executive officers for fiscal year 2011 were generally below the compensation committee's 50<sup>th</sup> percentile benchmark target. However, in determining to not increase base salaries for 2011, the compensation committee considered its implementation, discussed in greater detail below, of a 2011 short-term cash incentive program which, if paid out, would have the effect of providing for additional 2011 cash compensation to our executive officers. Our compensation committee believed that allocating a significant amount of our executive officers' cash compensation to their achievement of defined objectives under the 2011 short-term cash incentive plan closely aligned our executive officers' interests with those of our stockholders.

In January 2012, the compensation committee set base salary amounts for our executive officers for fiscal year 2012 as compared with 2011 amounts as follows: (i) Mr. Passeri, from \$400,000 to \$450,000; (ii) Mr. Gray, from \$300,000 to \$350,000; (iv) Mr. Noel, from \$215,000 to \$225,000 and (iv) Dr. Qian, remaining at \$275,000. Dr. Keegan served as our vice president of drug development until October 2011 and as such is no longer employed by us. The compensation committee made these January 2012 adjustments to base salaries for Messrs. Passeri, Gray and Noel primarily in recognition of the performance of our executive officers in leading Curis to meet a substantial portion of its key 2011 operating goals, our improved financial condition at January 2012 when compared to the start of the prior year, and our positive financial outlook for 2012, including FDA approval of Erivedge<sup>TM</sup> in the U.S. and anticipated approval in Europe.

#### *Discretionary Bonuses*

The compensation committee maintains the authority to award discretionary annual cash bonuses to our executive officers that are largely driven by both corporate performance against goals established at periodic board meetings and individual performance, as well as our financial capacity to pay such bonuses. The compensation committee does not grant bonuses every year, but granted bonuses in 2010 and 2011 to reward executive officer performance as our financial condition and outlook improved.

In January 2011, the compensation committee approved the payment of a discretionary one-time bonus to our executive officers of an aggregate of \$158,334. These discretionary bonuses ranged between 7% and 14% of the respective executive officer's 2010 base salary. The compensation committee determined to pay these bonuses in recognition for the achievement of key 2010 operating goals. When determining the amount of the bonus payments, the compensation committee considered, among other factors, the dollar amount of total bonus payments for 2010 and the size of such additional bonuses as a percentage of total potential payouts under the 2011 short-term cash incentive payment program (as further described in "2011 Short-Term Cash Incentive Plan" below).

One-time discretionary bonus payments were made to our executive officers in January 2011 as follows:

<u>Name</u>	<u>Discretionary bonus payment amount for 2010 performance</u>
Daniel R. Passeri .....	\$50,000
Michael P. Gray .....	\$41,667
Mark W. Noel .....	\$16,667
Changgeng Qian, Ph.D., M.D.(1) .....	\$33,333
Mitchell Keegan, Ph.D.(2) .....	\$16,667

(1) Dr. Qian ceased to serve as an officer in February 2012.

(2) Dr. Keegan ceased to serve as an officer in October 2011.

#### *2011 Short-Term Cash Incentive Plan*

Our compensation committee approved a 2011 short-term cash incentive award program for our executive officers. In order to set a target of total cash compensation at approximately the 50<sup>th</sup> percentile of peer companies, the compensation committee determined to combine potential cash compensation under this short-term incentive plan with fiscal year 2011 base salaries for our executive officers, which were generally below the compensation committee's 50<sup>th</sup> percentile target. Our compensation committee believed that allocating a meaningful amount of our executive officers' total cash compensation to the achievement of objectives under the 2011 short-term incentive plan aligned our executive officers' interests with those of our stockholders. Under this plan, our executive officers were entitled to receive a cash incentive award, which was contingent upon the compensation committee's determination that we achieved specified capital raising transaction objectives for the fiscal year ended December 31, 2011. Specifically, each executive officer who was serving as an executive officer on the date the award was paid would be entitled to receive a cash incentive award based upon our having actually received or having earned the unconditional right to receive, at any point on or after January 1, 2011 and on or before December 31, 2011, \$20.0 million of additional working capital such as in the form of unrestricted cash payments through milestones, license fees or other payments under existing or new collaborations and/or through the sale of equity to one or more third parties, provided that such equity sale is at a fair market value that exceeds the fair market value of the common stock as of January 7, 2011. The 2011 short-term cash incentive award program has been administered by the compensation committee and the compensation committee has retained the authority and discretion to amend, modify, alter or terminate the cash incentive program at any time based upon such factors as the compensation committee deems appropriate. The compensation committee established the potential cash payments under the 2011 short-term cash incentive award program based on its review of benchmarking information provided by Towers Watson and each executive officer's relative contribution to the achievement of our strategic goals. The compensation committee determined that it would award cash incentive payments to executive officers at 100% of target levels based upon the company's performance during the year, notwithstanding that the company did not fully meet the prescribed target for capital raising during 2011. On January 5, 2012, the compensation committee approved the payment of bonuses under this cash incentive award program to each of the named executive officers as follows:

<u>Name</u>	<u>Total 2011 Cash Incentive Amount Payable</u>	<u>Percentage of 2011 Base Salary</u>
Daniel R. Passeri .....	\$150,000	38%
Michael P. Gray .....	\$125,000	42%
Mark W. Noel .....	\$ 50,000	23%
Changgeng Qian, Ph.D., M.D.(1) .....	\$100,000	36%

(1) Dr. Qian ceased to serve as an officer in February 2012.

#### *2012 Short-Term Cash Incentive Plan*

On February 6, 2012, the compensation committee approved a 2012 short-term cash incentive program for executive officers. The cash incentive program is designed to motivate our executive officers to achieve specified performance objectives for fiscal year 2012 and to reward them for their achievement assuming those objectives are met. To be eligible, an executive officer must be designated by the compensation committee or independent board members as eligible to receive payments under the cash incentive program, must be serving as an executive officer at the time the award is paid and must have achieved a performance evaluation at a “meets expectations” or higher level within our evaluation framework. The compensation committee has determined that the following executive officers are currently eligible to participate in the cash incentive program: Daniel R. Passeri, Maurizio Voi, M.D., Michael P. Gray and Mark Noel.

The cash incentive program is administered by the compensation committee. The compensation committee has the authority and discretion to modify performance goals under the cash incentive program and has the right to amend, modify or terminate the cash incentive program at any time. The compensation committee has established the following target short-term incentive payment amounts, referred to herein as target amounts, for each executive officer:

<u>Designated Executive Officer</u>	<u>2012 Annual Base Salary</u>	<u>Target Incentive Compensation Payment as a Percentage of 2012 Annual Base Salary, Assuming Performance at the 100% Level</u>	
		(%)	(\$)
Daniel R. Passeri .....	\$ 450,000	45%	\$202,500
Maurizio Voi .....	\$ 400,000	35%	\$140,000
Michael P. Gray .....	\$ 350,000	35%	\$122,500
Mark Noel .....	\$ 225,000	25%	\$ 56,250
<b>Total .....</b>	<b>\$1,425,000</b>	<b>100%</b>	<b>\$521,250</b>

The compensation committee has established four weighted categories of corporate goals for 2012. The four categories of corporate goals for 2012 generally relate to the following:

- the establishment of the maximum tolerated dose of CUDC-101, the company’s lead candidate from its targeted cancer programs, in combination with cisplatin, a chemotherapeutic drug, and radiation in the company’s ongoing Phase I clinical trial in locally advanced head and neck cancer patients, and achievement of clinical trial enrollment;
- progress in preclinical efforts on an oral formulation of CUDC-101, including filing an investigational new drug application (“IND”) and commencing treatment of patients;
- progress in preclinical efforts on CUDC-907, a development candidate from the company’s targeted cancer programs, including filing an IND and commencing treatment of patients; and
- financial performance objectives, including cash management and capital objectives.

The foregoing four categories have been further delineated into three levels of potential achievement: “Threshold;” “Target;” and “Maximum.” Cash incentive payments may be paid based upon the degree to which each category of corporate goals has been achieved on this continuum, if at all. For each of the four categories,



achievement of performance at the “Threshold” level results in a weighted payment of no less than 50% of the target amount set forth above, achievement of performance at the “Target” level results in a weighted payment equal to 100% of the target amount set forth above, and achievement of performance at the “Maximum” level results in a weighted payment of no more than 150% of the target amount set forth above.

The awards, if any, generally will be paid in cash. The compensation committee has sole discretion, however, to pay an award using a combination of cash and equity or all equity, any such equity being issued pursuant to the company’s 2010 stock incentive plan. If the compensation committee determines that such payment will be made in whole or in part in the form of equity, the compensation committee shall have the sole discretion to determine the nature, amount and other terms of such equity award. Payment of the awards, if any, will be made after the completion of fiscal year 2012 and no later than March 15, 2013.

In the event of the consummation of a change in control of the company on or before December 31, 2012, short-term incentive amounts shall be paid out at 100% of target upon such change in control.

#### *Long-Term Incentive Program*

The compensation committee believes that long-term value creation is achieved through an ownership culture that encourages performance by our executive officers through the use of stock and stock-based awards. We have established our stock compensation plans to provide our employees, including our executive officers, with incentives to help align employee interests with the interests of our stockholders. The compensation committee believes that the use of stock-based awards is an important approach to achieving our compensation goals. The exercisability of stock options and the vesting of restricted stock awards are generally time-based. All the value received by the recipient from a stock option is based on the growth of the stock price above the option exercise price. Our executive officers have historically paid par value, \$0.01, per share of common stock underlying restricted stock awards. Accordingly, the value received by the recipient for a restricted stock award is equal to the difference between the fair market value of our common stock on the date the restricted stock award is granted and the \$0.01 per share paid for such restricted stock, plus any future growth of the stock price after such grant date.

We have not adopted stock ownership guidelines and our stock compensation plans have provided the principal method for our executive officers to acquire equity in our company. In December 2010, the compensation committee requested that Towers Watson research stock ownership guidelines for both executive officers and independent directors among development-stage life sciences companies. Towers Watson analyzed the most recent proxy filings of seventeen development-stage biopharma organizations, including the fourteen peer group companies used in the executive compensation analysis, to determine both the prevalence and design of executive stock ownership requirements. Of these seventeen organizations, only three (or 18%) employed stock ownership guidelines. Towers Watson also noted that all of our executive officers would fulfill competitive market levels of ownership when both common shares owned outright and vested in-the-money stock options were counted towards the guidelines. Based on Towers Watson’s findings, the compensation committee determined that it would continue to monitor the adoption of ownership policies among our peer group and the broader pre-commercial life sciences sector but would not presently recommend the implementation of stock ownership guidelines.

### *Stock Options*

Our 2010 stock incentive plan permits the grant of incentive and non-qualified stock options to our employees, directors and consultants. In the first quarter of 2010, our 2000 stock incentive plan expired in accordance with its terms and our 2000 director stock option plan had no available shares remaining under the plan. No additional awards will be made under these plans, although all outstanding awards under these plans will remain in effect until they are exercised or they expire in accordance with their terms.

The compensation committee or a majority of the independent directors serving on the board of directors review and approve stock option grants to our chief executive officer and the other executive officers. Stock option grants are made at the commencement of employment and then are generally granted annually in conjunction with the review of the individual performance of our executive officers. Grants may also be made following a significant change in job responsibilities or to meet other special retention or performance objectives. The review and approval of stock option awards to executive officers is based upon an assessment of individual performance, a review of each executive officer's existing long-term incentives and retention considerations. In appropriate circumstances, the compensation committee considers the recommendations of Mr. Passeri, our chief executive officer (except with respect to his own compensation) and Mr. McNab, the chairman of our board of directors. Stock options are granted with an exercise price equal to the fair market value of our common stock on the date of grant and typically vest and become exercisable as to 25% of the shares underlying the award after the first year and as to an additional 6.25% of the shares underlying the award in each subsequent quarter, based upon continued employment over a four-year period. The options generally expire ten years after the date of grant. In certain circumstances, stock options have and may be granted with different vesting terms, such as a shorter vesting period or performance-based vesting.

In January 2011, the compensation committee granted the following stock options pursuant to our 2010 stock incentive plan to our executive officers:

<u>Name</u>	<u>Number of Shares Underlying January 2011 Option Grants</u>
Daniel R. Passeri .....	200,000
Michael P. Gray .....	125,000
Mark W. Noel .....	60,000
Changgeng Qian, M.D., Ph.D. (1) .....	125,000
Mitchell Keegan, Ph.D. (2) .....	60,000

(1) Dr. Qian ceased to serve as an officer in February 2012.

(2) Dr. Keegan ceased to serve as an officer in October 2011.

The compensation committee believes that targeting the 75<sup>th</sup> percentile is consistent with its desire to emphasize equity opportunity, align executive officer and stockholder interests and manage our cash consumption. In determining the size of each stock option grant awarded to our named executive officers in 2011, the compensation committee targeted the 75<sup>th</sup> percentile of value for the peer group established by Towers Watson, data from the related Radford Global Life Sciences Compensation Survey for long-term incentive compensation as well the compensation committee's desire to preserve adequate common shares subject to future stock options and other stock awards that would be granted under the 2010 stock incentive plan. The 2011 awards to our chief executive officer and our chief operating and financial officer are significantly below the compensation committee's goal of the 75<sup>th</sup> percentile of benchmark companies and are approximately 20% below

the 75<sup>th</sup> percentile target for our other executive officers. In total, the underlying value of the stock options awarded to our executive officers was significantly below the compensation committee's goal of the 75<sup>th</sup> percentile of benchmark companies and above the 50<sup>th</sup> percentile of this benchmark. After considering the factors described above, the compensation committee decided to grant the number of shares subject to stock option awards listed above primarily to preserve the currently available pool of shares that may be used for future awards under the 2010 stock incentive plan.

In January 2012, the compensation committee granted the following stock options from our 2010 stock incentive plan to our executive officers:

<u>Name</u>	<u>Number of Shares Underlying January 2012 Option Grants</u>	<u>Percentage Increase/ (Decrease) from Prior Year Grants</u>
Daniel R. Passeri . . . . .	400,000	100%
Michael P. Gray . . . . .	250,000	100%
Mark W. Noel . . . . .	80,000	33%
Changgeng Qian, M.D., Ph.D. (1). . . . .	—	(100%)

(1) Dr. Qian ceased to serve as an officer in February 2012.

The number of shares awarded to our executive officers in January 2012 increased as compared to our 2011 grants, both in absolute numbers and in underlying value at the time of grant. The compensation committee increased stock option awards in 2012, particularly to our chief executive officer and our chief operating and financial officer in part because of the 2011 contribution of the chief executive officer and chief operating and financial officer during 2011 in the company obtaining its primary 2011 operating goals as well as the fact that the 2011 awards were much lower than the compensation committee's 75<sup>th</sup> percentile target.

#### *Restricted Stock Awards*

Our 2010 stock incentive plan permits the issuance of restricted stock awards to our employees, directors and consultants. The compensation committee generally does not make grants of restricted stock awards to our executive officers and no restricted stock awards were granted in 2011. The compensation committee generally favors the award of stock options over restricted stock in its annual compensation of our executive officers. Since the compensation committee grants stock options with exercise prices that are equal to the fair market value of our common stock on the grant date, the compensation committee believes that stock options closely align our executive officers' interests with those of our stockholders as such stock options only generate value to our executive officers if the fair market value of our common stock rises.

#### *2010 Employee Stock Purchase Plan*

Executive officers are eligible to participate in our 2010 employee stock purchase plan. The plan permits participant employees to purchase company stock through payroll deductions of up to 15% of total cash compensation. The price of the stock is 85% of the lower of the fair market value of the stock at the beginning or the end of the offering period. In 2011, none of our executive officers participated in the 2010 employee stock purchase plan.

### *Other Compensation – Employee Benefits*

Our employees, including our executive officers, are entitled to various employee benefits such as medical and dental expense coverage, flexible spending accounts, various insurance programs, an employee assistance program and paid time off. Executive officers are eligible to participate in our 401(k) retirement plan. Matching contributions to the 401(k) plan are at the discretion of the compensation committee of the board of directors.

### *Change in Control and Severance Payments*

Each of our executive officers is party to an agreement or offer letter that obligates us to make payments to such executive officer in the event we terminate the executive officer's employment without cause or the executive officer resigns for good reason (as defined in the applicable agreement or offer letter). We believe that our severance program is aligned with other comparable biotechnology companies and provides our executive officers with income protection in the event of an unplanned separation from employment. In addition, we are also obligated to make payments to each of our executive officers if he is terminated under specified circumstances within twelve months after a change in control. This is a so-called "double trigger" change in control arrangement because it provides for severance benefits only in the event of a change in control, the first trigger, followed by an employment termination under specified circumstances, the second trigger. Our 2000 and 2010 stock incentive plans provide that all plan participants, including our executive officers, are entitled to accelerated vesting of stock options and/or restricted stock awards upon certain events. In the event that a change in control occurs, 50% of the then unvested options of each plan participant, including executive officers, would become immediately exercisable and the restrictions underlying 50% of any restricted stock awards would lapse. In the event any executive officer leaves within one year after a change in control without cause or for good reason (each as defined in the applicable plan), then all remaining unvested stock options and restricted stock awards will become fully vested. Our 2000 and 2010 stock incentive plans generally define a change in control as a merger by us with or into another company or a sale of all or substantially all of our assets. We have determined to provide for these change in control arrangements because we recognize that, as is the case with many publicly-held corporations, the possibility of a change in control of our company exists and such possibility, and the uncertainty and questions which it may raise among our executive officers, could result in the departure or distraction of executive officers to the detriment of our company and our stockholders. As a consequence, our compensation committee has determined to provide such change in control related benefits to reinforce and encourage the continued employment and dedication of our executive officers without distraction from the possibility of a change in control and related events and circumstances.

Our change in control and severance arrangements with our executive officers do not obligate us to make any additional payments to "gross-up" any such compensation payable to such executive officers in order to offset income tax liabilities.

For a further description of the foregoing arrangements, see "Summary Compensation Table," "Employment Agreements" and "Potential Payments Upon Termination or Change in Control."

### **Tax and Accounting Considerations**

We account for equity compensation paid to our employees under the rules of FASB Codification Topic 718 (formerly FAS 123(R)), which require us to estimate and record an expense over the service period of the award. Accounting rules also require us to record cash compensation as an expense at the time the obligation is accrued. To date, these accounting requirements have not impacted our executive compensation programs and practices.

The Internal Revenue Service, pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended, generally disallows a tax deduction for compensation in excess of \$1.0 million paid to our chief executive officer and to each other officer (other than our chief executive officer and our chief financial officer) whose compensation is required to be reported to our stockholders pursuant to the Exchange Act by reason of being among the three most highly paid executive officers. Certain compensation, including qualified performance-based compensation, will not be subject to the deduction limit if certain requirements are met. The compensation committee reviews the potential effect of Section 162(m) periodically and uses its judgment to authorize compensation payments that may be subject to the limit when the compensation committee believes that such payments are appropriate and in the best interests of us and our stockholders, after taking into consideration changing business conditions and the performance of our employees.

### Summary Compensation Table

The following table sets forth information regarding compensation earned by each of our named executive officers for the fiscal years ending December 31, 2011, 2010 and 2009.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)(1)	Stock Awards (\$)	Option Awards (\$)(2)	All Other Compensation (\$)	Total (\$)
Daniel R. Passeri . . . . .	2011	400,000	150,000	—	281,440	9,800(5)	\$ 841,240
Chief Executive Officer	2010	391,923	200,000	—	577,155	7,350(5)	1,176,428
	2009	311,538(3)	—	—	226,410	19,000(5)	556,948
Michael P. Gray . . . . .	2011	300,000	125,000	—	175,900	9,800(5)	610,700
Chief Operating Officer and Chief Financial Officer	2010	295,961	166,667	—	353,503	7,350(5)	823,481
	2009	259,615(3)	—	51,423(4)	135,846	19,000(5)	465,884
Mark W. Noel . . . . .	2011	215,000	50,000	—	84,432	8,600(5)	358,032
Vice President, Technology Management and Intellectual Property	2010	212,900	66,667	—	158,708	6,387(5)	444,662
	2009	196,269(3)	—	—	56,603	14,829(5)	267,701
Changpeng Qian (7) . . . .	2011	275,000	100,000	—	175,900	9,800(5)	560,700
Senior Vice President, Research and Preclinical Development	2010	270,961	133,333	—	353,503	7,350(5)	765,147
	2009	233,654(3)	—	—	135,846	18,546(5)	388,046
Mitchell Keegan (8) . . . .	2011	192,308	—	—	84,432	8,526(6)	285,266
Vice President, Development	2010	247,981	66,667	—	86,514	7,350(5)	408,512
	2009	233,654(3)	—	—	151,474	12,808(5)	397,936

- (1) Consists of bonuses approved by the compensation committee and accrued in our financial statements at December 31, 2011 and 2010. All of the 2011 bonuses earned were not paid until January 2012, and a portion of each officer's bonus earned in 2010, \$158,333 in the aggregate, was not paid until January 2011.
- (2) The amounts in this column reflect the aggregate grant date fair value of equity awards granted during the respective fiscal year, computed in accordance with FASB Codification Topic 718 and other relevant guidance, for awards pursuant to our 2000 and 2010 stock incentive plans. Assumptions used in the calculation of these amounts are included in footnote 5 to our audited financial statements for the fiscal year

ended December 31, 2011 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 29, 2012. During 2007, the officers were issued certain options, the exercisability of which was tied to a performance condition, the occurrence of which was not probable at the date of grant. The related performance conditions were met in 2010. The following table denotes the maximum value of these 2007 options which are included in the Summary Compensation Table:

<u>Name</u>	<u>Maximum Value of 2007 Performance Condition Options</u>
Daniel R. Passeri .....	\$288,775
Michael P. Gray .....	173,265
Mark W. Noel .....	72,194
Changgeng Qian (7) .....	173,265

- (3) This amount reflects 27 pay periods in 2009 (vs. 26 pay periods in each of 2011 and 2010) because the pay period ending January 1, 2010 was paid on December 31, 2009 due to a bank holiday.
- (4) This amount reflect the dollar amount recognized for financial statement reporting purposes for fiscal 2009 in accordance with FASB Codification Topic 718, of an award pursuant to our 2000 stock incentive plan of 79,113 shares of restricted stock at a purchase price of \$0.01 per share, on October 24, 2008, when the fair market value was \$0.79 per share and includes only that portion of the stock award that vested during 2009. Assumptions used in the calculation of this amount are included in footnote 5 to our audited financial statements for the fiscal year ended December 31, 2009 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 3, 2010.
- (5) Consists of 401(k) contributions made by us.
- (6) Represents Dr. Keegan's earned vacation that was paid to him upon his resignation in October 2011.
- (7) Dr. Qian ceased to serve as an officer in February 2012.
- (8) Dr. Keegan ceased to serve as an officer in October 2011.

#### **Grants of Plan-Based Awards**

The following table sets forth information regarding awards under our 2010 stock incentive plan to our named executive officers during the fiscal year ended December 31, 2011.

<u>Name</u>	<u>Grant Date</u>	<u>All Other Option Awards: Number of Securities Underlying Options (#) (1)</u>	<u>Exercise or Base Price of Option Awards (\$/Sh) (2)</u>	<u>Grant Date Fair Value of Stock and Option Awards (3)</u>
Daniel R. Passeri .....	01/07/11	200,000	\$2.15	\$281,440
Michael P. Gray .....	01/07/11	125,000	2.15	175,900
Mark W. Noel .....	01/07/11	60,000	2.15	84,432
Changgeng Qian (4) .....	01/07/11	125,000	2.15	175,900
Mitchell Keegan (5) .....	01/07/11	60,000	2.15	84,432

- (1) Such stock options will expire 10 years from date of grant. Such stock options will vest over a period of four years with 25% of the shares underlying the grant vesting on January 7, 2012 and an additional 6.25% of the shares underlying the grant vesting on each successive three-month period until the option is fully vested on

the fourth anniversary of the grant date, subject to the continued employment of the executive officer. Under the terms of the 2010 stock incentive plan, a change in control occurs in the event we merge with or into another company or we sell all or substantially all of our assets. At the time of a change in control, 50% of the then unvested options held by each plan participant, including executive officers, would become immediately exercisable and the restrictions on restricted stock awards would lapse with respect to 50% of the number of shares that otherwise would have first become free from restrictions after the date of the change in control. In addition, under the terms of the 2010 stock incentive plan, in the event an executive officer terminates his employment for good reason (as defined in the plan) or we terminate the executive officer without cause (as defined in the plan) within one year after a change in control, then all options and restricted stock held by the executive officer would become fully vested upon such termination.

- (2) The exercise price per share is equal to the closing price per share of our common stock on the date of grant.
- (3) The amounts shown in this column represent the total grant date fair value of each stock and option award as determined in accordance with FASB Codification Topic 718.
- (4) Dr. Qian ceased to serve as an officer in February 2012.
- (5) Dr. Keegan ceased to serve as an officer in October 2011.

We have entered into employment agreements with our named executive officers, as described below under “Employment Agreements” and “Indemnification of Executive Officers.”

Base salary accounted for approximately 59.5% of the total compensation of the named executive officers for 2009. Salary and bonus payments accounted for approximately 56.7% of the total compensation of the named executive officers for 2010. Salary and bonus payments accounted for approximately 68.1% of the total compensation of the named executive officers for 2011.

### Outstanding Equity Awards at Fiscal Year-End

The following table summarizes the outstanding equity awards held by our named executive officers as of December 31, 2011.

Name	Number of Securities Underlying Unexercised Options (#)	Number of Securities Underlying Unexercised Options (#) (1)	Option Exercise Price (\$)	Option Expiration Date
	Exercisable	Unexercisable		
Daniel R. Passeri .....	—	200,000	\$2.15	1/07/2021
	87,500	112,500	\$2.27	2/02/2020
	206,250	93,750	\$1.07	2/05/2019
	202,000	—	\$0.79	10/24/2018
	281,250	18,750	\$1.43	1/25/2018
	500,000	—	\$1.39	6/06/2017
	390,000	—	\$1.57	5/31/2016
	175,000	—	\$3.98	6/01/2015
	175,000	—	\$4.56	6/25/2014
	450,000	—	\$2.43	5/13/2013
	76,250	—	\$1.09	9/25/2012
	95,150	—	\$1.50	6/05/2012

<u>Name</u>	<b>Number of Securities Underlying Unexercised Options (#) Exercisable</b>	<b>Number of Securities Underlying Unexercised Options (#) (1) Unexercisable</b>	<b>Option Exercise Price (\$)</b>	<b>Option Expiration Date</b>
Michael P. Gray .....	—	125,000	\$2.15	1/07/2021
	54,687	70,313	\$2.27	2/02/2020
	123,750	56,250	\$1.07	2/05/2019
	168,750	11,250	\$1.43	1/25/2018
	300,000	—	\$1.39	6/06/2017
	200,000	—	\$1.57	5/31/2016
	75,000	—	\$3.98	6/01/2015
	75,000	—	\$4.56	6/25/2014
	160,000	—	\$4.95	12/11/2013
	50,000	—	\$2.43	5/13/2013
	26,250	—	\$1.09	9/25/2012
	42,844	—	\$1.50	6/05/2012
Mark W. Noel .....	—	60,000	\$2.15	1/07/2021
	26,250	33,750	\$2.27	2/02/2020
	51,562	23,438	\$1.07	2/05/2019
	43,000	—	\$0.79	10/24/2018
	70,312	4,688	\$1.43	1/25/2018
	125,000	—	\$1.39	6/06/2017
	100,000	—	\$1.57	5/31/2016
	50,000	—	\$3.98	6/01/2015
	50,000	—	\$4.56	6/25/2014
	70,000	—	\$2.43	5/13/2013
	48,000	—	\$1.09	9/25/2012
	74,100	—	\$1.50	6/05/2012
Changgeng Qian (2) .....	—	125,000	\$2.15	1/05/2021
	54,687	70,313	\$2.27	2/02/2020
	123,750	56,250	\$1.07	2/05/2019
	51,000	—	\$0.79	10/24/2018
	168,750	11,250	\$1.43	1/25/2018
	300,000	—	\$1.39	6/06/2017
	100,000	—	\$1.57	9/13/2016
	40,000	—	\$1.57	5/31/2016
	16,000	—	\$4.03	1/10/2016
	24,000	—	\$3.98	6/01/2015
	24,000	—	\$4.56	6/25/2014
	35,000	—	\$2.43	5/13/2013
	9,375	—	\$1.09	9/25/2012
	20,125	—	\$1.50	6/05/2012
Mitchell Keegan (3) .....	7,500	—	\$2.27	1/04/2012

- (1) Such stock options will expire 10 years from date of grant. These stock options will vest over a period of four years with 25% of the shares underlying the grant vesting on the first anniversary of the grant date and an additional 6.25% of the shares underlying the grant vesting during each successive three-month period until the option is fully vested on the fourth anniversary of the grant date, subject to the continued employment of the executive officer unless as otherwise noted. Under the terms of the 2000 and 2010 stock



incentive plans, a change in control occurs in the event we merge with or into another company or we sell all or substantially all of our assets. At the time of a change in control, 50% of the then unvested options held by each plan participant, including executive officers, would become immediately exercisable and the restrictions on restricted stock awards would lapse with respect to 50% of the number of shares that otherwise would have first become free from restrictions after the date of the change in control. In addition, under the terms of the 2000 and 2010 stock incentive plans, in the event an executive officer terminates his employment for good reason (as defined in the plan) or we terminate the executive officer without cause (as defined in the plan) within one year after a change in control, then all options and restricted stock held by the executive officer would become fully vested upon such termination.

- (2) Dr. Qian ceased to serve as an officer in February 2012.
- (3) Dr. Keegan ceased to serve as an officer in October 2011.

### Option Exercises

The following table summarizes, for each of our named executive officers, each exercise of stock options during 2011.

<u>Name</u>	<u>Option Awards</u>	
	<u>Number of Shares Acquired on Exercise (#)</u>	<u>Value Realized on Exercise (\$)</u>
Daniel R. Passeri .....	125,000	15,807
Michael P. Gray .....	—	—
Mark W. Noel .....	—	—
Changgeng Qian, M.D., Ph.D. (1) .....	—	—
Mitchell Keegan (2) .....	222,812	688,882

- (1) Dr. Qian ceased to serve as an officer in February 2012.
- (2) Dr. Keegan ceased to serve as an officer in October 2011.

### Employment Agreements

We are party to the following employment arrangements with our executive officers.

*Daniel R. Passeri.* On September 18, 2007, we entered into an employment agreement with Mr. Passeri. The agreement is intended to comply with the applicable provisions of Section 409A of the Internal Revenue Code of 1986, as amended, and the final Treasury regulations and guidance issued thereunder. Under the agreement, Mr. Passeri will serve as our president and chief executive officer for the period that commenced on September 18, 2007 and ends on December 31, 2012. Mr. Passeri's base salary was set at \$400,000 per annum subject to annual review by the board. Mr. Passeri's agreement was also amended to provide for the payment of Mr. Passeri's fees for preparation of his tax return by a tax professional. Mr. Passeri is entitled to participate in our medical and other benefit programs and may be entitled to receive an annual bonus based on the achievement of specific objectives established by the board. Mr. Passeri is entitled to receive severance benefits under the agreement in the event of his termination without cause or for good reason (as defined in the agreement) and he is also entitled to receive certain payments if he is terminated within one year after a change in control. For a description and quantification of such severance and change in control benefits, see "Potential Payments Upon Termination or Change In Control." In addition, the agreement provides for certain indemnification provisions. For a description of such indemnification provisions, see "Indemnification of Executive Officers." On October 24, 2008, Mr. Passeri's agreement was amended to reduce Mr. Passeri's base salary from \$400,000 to

\$300,000 and in consideration of such reduction, Mr. Passeri received an option to purchase 202,000 shares of our common stock at an exercise price of \$0.79 per share, with vesting as to one-twelfth of the shares underlying such option on November 24, 2008 and on the 24<sup>th</sup> day of each month thereafter until the option became fully vested on October 24, 2009. On December 10, 2010, Mr. Passeri's agreement was amended to reflect certain provisions of Section 409A of the Internal Revenue Code of 1986, as amended, and the final Treasury regulations and guidance issued thereunder.

*Michael P. Gray.* On December 15, 2003, we entered into an employment agreement with Mr. Gray, which was amended on October 31, 2006. Under the agreement, Mr. Gray was promoted to Vice President, Finance and Chief Financial Officer effective as of November 27, 2003 at an initial base salary of \$185,000 per annum, subject to review as part of our performance review program. In addition, Mr. Gray received an option to purchase 160,000 shares of our common stock to vest over four years, 25% after the first year and 6.25% per quarter over the remainder of the vesting period. On December 14, 2006, Mr. Gray was promoted from Senior Vice President of Finance and Chief Financial Officer to Chief Operating Officer and Chief Financial Officer. On October 24, 2008, Mr. Gray's agreement was amended to reduce Mr. Gray's base salary from \$300,000 to \$250,000 and in consideration of such reduction, Mr. Gray received a restricted stock award of 79,113 shares, at a purchase price of \$0.01 per share, with vesting as to one-twelfth of the shares on November 24, 2008 and on the 24<sup>th</sup> day of each month thereafter until the shares became fully vested on October 24, 2009. Mr. Gray is entitled to receive severance benefits under the agreement in the event of his termination without cause or for good reason (as defined in the agreement) and he is also entitled to receive certain payments if he is terminated within one year after a change in control. For a description and quantification of such severance and change in control benefits, see "Potential Payments Upon Termination or Change In Control." In addition, the agreement provides for certain indemnification provisions. For a description of such indemnification provisions, see "Indemnification of Executive Officers." On December 10, 2010, Mr. Gray's agreement was amended to reflect certain provisions of Section 409A of the Internal Revenue Code of 1986, as amended, and the final Treasury regulations and guidance issued thereunder.

*Mark W. Noel.* On January 11, 2001, we entered into an employment agreement with Mr. Noel, which was amended on October 31, 2006. Under the agreement, Mr. Noel serves as our Vice President of Technology Management and Intellectual Property, at an initial base salary of \$160,000 per annum, subject to review as part of our performance review program. In addition, Mr. Noel received an option to purchase 60,000 shares of our common stock to vest over four years, 25% after the first year and 6.25% per quarter over the remainder of the vesting period. On October 24, 2008, Mr. Noel's agreement was amended to reduce Mr. Noel's base salary from \$210,000 to \$189,000 and in consideration of such reduction, Mr. Noel received an option to purchase 43,000 shares of our common stock at an exercise price of \$0.79 per share, with vesting as to one-twelfth of the shares underlying such option on November 24, 2008 and on the 24<sup>th</sup> day of each month thereafter until the option became fully vested on October 24, 2009. Mr. Noel is entitled to receive severance benefits under the agreement in the event of his termination without cause or for good reason (as defined in the agreement) and he is also entitled to receive certain payments if he is terminated within one year after a change in control. For a description and quantification of such severance and change in control benefits, see "Potential Payments Upon Termination or Change In Control." In addition, the agreement provides for certain indemnification provisions. For a description of such indemnification provisions, see "Indemnification of Executive Officers." On December 10, 2010, Mr. Noel's agreement was amended to reflect certain provisions of Section 409A of the Internal Revenue Code of 1986, as amended, and the final Treasury regulations and guidance issued thereunder.

*Changgeng Qian, M.D., Ph.D.* Dr. Qian ceased to serve as an officer in February 2012. We were a party to an employment agreement with Dr. Qian pursuant to which he was entitled to receive severance benefits. Dr. Qian received the following benefits in accordance with a Severance Agreement and General Release that we entered into with Dr. Qian and that became binding and effective on February 24, 2012: (i) a lump-sum payment equivalent to one-half times his base salary rate in effect as of February 16, 2012; and (ii) if Dr. Qian elects to continue receiving group health insurance pursuant to the federal “COBRA” law, payment by us of the premium for six months following February 16, 2012. We also agreed to engage Dr. Qian as a consultant pursuant to the terms of a consulting agreement that Dr. Qian entered into with us on February 24, 2012.

#### **Indemnification of Executive Officers**

Our certificate of incorporation provides indemnification of our executive officers for any threatened, pending or completed action, suit or proceeding whether civil, criminal, administrative or investigative (other than an action or claim by or in the right of the company) by reason of the fact that such person serves as an executive officer, to the maximum extent permitted by the General Corporation Law of Delaware. The certificate of incorporation further provides that executive officers may be entitled to additional indemnification, under any agreement or vote of the directors.

Each of our executive officer employment agreements also provides that we will indemnify each such executive officer for claims arising in his capacity as our executive officer, provided that he acted in good faith and in a manner that he reasonably believed to be in, or not opposed to, our best interests. With respect to any criminal proceeding, the executive officer must have no reasonable cause to believe that the conduct was unlawful. If the claim is brought by us or on our behalf, we will not be obligated to indemnify the executive officer if the executive officer is found liable to us, unless the court determines that, despite the adjudication of liability, in view of all the circumstances of the case the executive officer is fairly and reasonably entitled to be indemnified. In the event that we do not assume the defense of a claim against the executive officer, we are required to advance his expenses in connection with his defense, provided that he undertakes to repay all amounts advanced if it is ultimately determined that he is not entitled to be indemnified by us. We will require that any successor to our business assumes and agrees to perform our obligations under the indemnification provisions.

In connection with our indemnification obligations we have and intend to maintain director and officer liability insurance, if available.

#### **Potential Payments Upon Termination or Change in Control**

Each of the above-described employment agreements with our executive officers also provides that in the event we terminate the executive officer’s employment without cause or if the executive officer resigns for good reason (each as defined in the agreements) including a termination within twelve months after a change in control of the company, the executive officer will receive: (1) his base salary (as defined in the agreement) accrued through the last day of employment; (2) continuation of his then base salary or a portion thereof for the periods and amounts described in the table below, and (3) payment of a portion of the executive officer’s COBRA premiums, which is calculated as the difference between the COBRA premium and the amount as paid by the employee for medical/dental insurance, for the periods and amounts described in the table below. In order for our executive officers to receive these severance payments, the executive officer must execute a general release of all claims against the company, its employees, officers, directors and agents in a form acceptable to us.

If any of Messrs. Gray or Noel are considered “specified employee(s)” on the date of their termination within the meaning of Section 409A(a)(2)(B)(i) of the Internal Revenue Code and the regulations thereunder, and any payments to be paid or provided to these executive officers constitute “nonqualified deferred compensation” within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended, then the severance and benefit payments per the table below will be delayed by a period of six months and will be paid in a lump sum in the seventh month following the date of termination. In the case of Mr. Passeri, if Mr. Passeri is considered a “specified employee” on the date of his termination, then Mr. Passeri’s severance and benefit payments will be paid within the short-term deferral period, which means the period ending on the later of the 15th day of the third month following the end of the employee’s tax year in which Mr. Passeri’s separation from service occurs and the 15th day of the third month following the end of our tax year in which Mr. Passeri’s separation from service occurs, and shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A of the Code. If Mr. Passeri’s severance and benefit payments are not paid within the short-term deferral period then such payments will be delayed by a period of six months and will be paid in a lump sum in the seventh month following the date of termination.

Pursuant to the terms of our 2000 and 2010 stock incentive plans, at the time of a change in control, 50% of the then-unvested options to purchase our common stock held by each plan participant, including executive officers, would become immediately exercisable and the forfeiture restriction on all outstanding restricted stock awards would lapse with respect to 50% of the number of shares that otherwise would have first become free from such forfeiture restrictions after the date of the change in control. In addition, in the event an executive officer terminates his employment for good reason (as defined in the applicable plan) or we terminate the executive officer without cause (as defined in the applicable plan) within one year after such change in control, then all remaining unvested options and restricted stock held by the executive officer would become fully vested and/or free of all forfeiture restrictions, as applicable.

The table below sets forth the estimated benefits provided to each of our named executive officers upon a termination event described above, assuming such termination event occurred on December 31, 2011, the last day of our most recently completed fiscal year.

<u>Name</u>	<u>Severance Term in Months</u>	<u>Severance Upon Termination (\$)</u>	<u>Value of Equity Acceleration (1)</u>	<u>Benefits Upon Termination (\$)</u>	<u>Total Benefits</u>
Daniel R. Passeri . . . . . Chief Executive Officer	Twelve	\$400,000	\$588,250	\$12,773	\$1,001,023
Michael P. Gray, . . . . . Chief Operating Officer and Chief Financial Officer	Six	\$150,000	\$362,665	\$ 6,387	\$ 519,052
Mark W. Noel, . . . . . Vice President Technology Management and Intellectual Property	Six	\$107,500	\$166,492	\$ 6,387	\$ 280,379

- (1) Represents the value of that portion of each named executive officer’s in-the-money stock options that would accelerate upon a change in control, assuming such change in control occurred on December 31, 2011, after deducting the exercise price and based upon the \$4.68 closing price of our common stock on the Nasdaq Global Market on December 31, 2011. As noted above, pursuant to the terms of our stock incentive plans, at the time of a change in control, 50% of the then-unvested options become immediately exercisable and the forfeiture restrictions on all outstanding restricted stock awards lapse with respect to 50% of the

number of shares that otherwise would have first become free from such forfeiture restrictions after the date of the change in control. In addition, in the event an executive officer terminates his employment for good reason (as defined in the applicable plan) or we terminate the executive officer without cause (as defined in the applicable plan) within one year after such change in control, then all remaining unvested options and restricted stock held by the executive officer would become fully vested and/or free of all forfeiture restrictions, as applicable. Assuming that such termination was to occur within one year after a change of control, the total value of accelerated in-the-money stock options would be as follows: Mr. Passeri, \$1,176,500; Mr. Gray, \$725,329; and Mr. Noel, \$332,985.

- (2) Dr. Qian ceased to serve as an officer in February 2012. For a description of the severance arrangement with Dr. Qian, see “Employment Agreements.”

### Director Compensation Table

The following table sets forth a summary of the compensation earned by or paid to our non-employee directors in 2011:

<u>Name</u>	<u>Fees Earned or Paid In Cash(\$)</u>	<u>Option Awards (\$)(1)(2)</u>	<u>All Other Compensation (\$)</u>	<u>Total (\$)</u>
Susan B. Bayh .....	\$ 30,000	\$ 35,180	\$ —	\$ 65,180
Joseph M. Davie (3) .....	13,557	35,180	—	48,737
Martyn D. Greenacre .....	38,500	35,180	—	73,680
Kenneth I. Kaitin .....	32,750	35,180	—	67,930
Robert E. Martell .....	11,943(4)	55,228(4)	—	67,171
James R. McNab, Jr. ....	133,500(5)	119,612	23,396(6)	276,508
Marc Rubin .....	29,750	35,180	—	64,930
James R. Tobin .....	32,000	35,180	—	67,180

- (1) The amounts in this column reflect the grant date fair value of awards made to such individual in accordance with FASB Codification Topic 718 and other relevant guidance, excluding forfeitures, for awards in 2011 pursuant to our 2010 stock incentive plan. Assumptions used in the calculation of these amounts are included in footnote 5 to our audited financial statements for the fiscal year ended December 31, 2011 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 29, 2012.
- (2) At December 31, 2011, each of our current non-employee directors held options to purchase shares of our common stock as follows:

<u>Director</u>	<u>Aggregate Number of Stock Options</u>
Susan B. Bayh .....	259,045
Martyn D. Greenacre .....	400,000
Kenneth I. Kaitin .....	165,000
Robert E. Martell .....	25,000
James R. McNab, Jr. ....	297,500
Marc Rubin .....	50,000
James R. Tobin .....	225,000

- (3) Dr. Davie retired from the board on September 13, 2011, and the fees earned in 2011 are through this date.
- (4) Dr. Martell joined the board on September 14, 2011, and the fees earned in 2011 are from this date through December 31, 2011. Upon joining the board, Dr. Martell was granted an option to purchase 25,000 shares of our common stock that will vest over a period of four years with 25% of the shares underlying the grant vesting on the first anniversary of the grant date and an additional 6.25% of the shares vesting during each successive three-month period until the option is fully vested on the fourth anniversary of the grant date, subject to Dr. Martell's continued participation on the board. The options will expire 10 years from date of grant.
- (5) On June 1, 2005, we entered into an agreement for service as chairman of the board of directors with Mr. McNab. As chairman of the board of directors, Mr. McNab receives a cash payment of \$10,000 per month plus board attendance fees.
- (6) Consists of payments made by us to reimburse the cost of Mr. McNab's annual health insurance expense.

Non-employee directors receive an initial stock option grant upon election to the board and annual stock option grants upon reelection to the board. In addition, non-employee directors, other than Mr. McNab, receive an annual cash retainer of \$15,000. Non-employee directors who serve as committee chairpersons of the nominating and corporate governance committee or of the compensation committee receive an additional \$5,000 payment for such committee chairperson services. Non-employee directors who serve as the committee chairperson of the audit committee receive an additional payment of \$10,000 for such committee chairperson services. Directors are paid additional cash compensation in the amount of \$1,500 for each board or committee meeting attended in person and \$750 for telephonic meetings. In addition, directors are reimbursed for reasonable out-of-pocket expenses that are incurred due to attendance at board or committee meetings. Directors who are our employees are not compensated for their attendance at board or committee meetings.

#### **Indemnification of Directors**

Our certificate of incorporation provides indemnification of our directors for any threatened, pending or completed action, suit or proceeding whether civil, criminal, administrative or investigative (other than an action or claim by or in the right of the company) by reason of the fact of that such person serves as a director, to the maximum extent permitted by the General Corporation Law of Delaware. The certificate of incorporation further provides that directors may be entitled to additional indemnification, under any agreement or vote of the directors.

On June 1, 2005 we entered into indemnification agreements with Messrs. Greenacre, McNab and Tobin, Dr. Kaitin and Ms. Bayh. We entered into an indemnification agreement with Dr. Rubin following his election to the board on June 3, 2010 and with Dr. Martell following his election to the board on September 14, 2011. The indemnification provisions apply to each such director and state that we will indemnify him or her for claims arising in his or her capacity as our director, provided that he or she acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, our best interests. With respect to any criminal proceeding, the director must have no reasonable cause to believe that the conduct was unlawful. If the claim is brought by us or on our behalf, we will not be obligated to indemnify the director if the director is found liable to us, unless the court determines that, despite the adjudication of liability, in view of all the circumstances of the case, the director is fairly and reasonably entitled to be indemnified. In the event that we do not assume the defense of a claim against the director, we are required to advance his or her expenses in connection with his or her defense, provided that he or she undertakes to repay all amounts advanced if it is ultimately determined that he or she is not entitled to be indemnified by us. We will require that any successor to our business assumes and agrees to perform our obligations under the indemnification provisions.

In connection with our indemnification obligations we have and intend to maintain director and officer liability insurance, if available on reasonable terms. See “Indemnification of Executive Officers” for a discussion of our indemnification arrangements with Mr. Passeri.

### Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2011 regarding compensation plans (including individual compensation arrangements) under which our equity securities are authorized for issuance.

	(a)	(b)	(c)
	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (1)
Equity compensation plans approved by security holders . . . . .	11,094,241	\$2.13	4,704,166
Equity compensation plans not approved by security holders . . . . .	—	—	—
Total . . . . .	<u>11,094,241</u>	<u>\$2.13</u>	<u>4,704,166</u>

(1) Comprised of 4,367,000 shares available for grant under the 2010 Stock Incentive Plan and 337,166 shares available for sale under the 2010 Employee Stock Purchase Plan. Both plans were approved by our stockholders in June 2010.

### Compensation Committee Interlocks and Insider Participation

During the fiscal year ended December 31, 2011, the members of our compensation committee were Ms. Bayh, Mr. Tobin and Dr. Kaitin, none of whom was a current or former officer or employee and none of whom had any related person transaction involving the company.

During the fiscal year ended December 31, 2011, none of our executive officers served as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that had one or more of its executive officers serving as a member of our board of directors or our compensation committee.

### Compensation Committee Report

The compensation committee has reviewed and discussed the Compensation Discussion and Analysis, required by Item 402(b) of Regulation S-K with Curis’ management. Based on this review and discussion, the compensation committee recommended to our board of directors that the Compensation Discussion and Analysis be included in this proxy statement.

Submitted by the compensation committee of our board of directors.

James R. Tobin (Chair)  
Susan B. Bayh  
Kenneth I. Kaitin

## **PROPOSAL 2—RATIFICATION OF THE APPOINTMENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The audit committee has selected PricewaterhouseCoopers LLP as our independent registered public accounting firm for the year ending December 31, 2012. PricewaterhouseCoopers LLP has served as our independent registered public accounting firm since April 26, 2002. Although stockholder approval of the audit committee's selection of PricewaterhouseCoopers LLP is not required by law, the board and the audit committee believe that it is advisable to give stockholders an opportunity to ratify this selection. If the stockholders do not ratify the selection of PricewaterhouseCoopers LLP, the audit committee will reconsider the matter. A representative of PricewaterhouseCoopers LLP is expected to be present at the meeting to respond to appropriate questions and to make a statement if he or she so desires.

### **Board Recommendation**

**OUR BOARD OF DIRECTORS BELIEVES THAT THE RATIFICATION OF THE SELECTION OF PRICEWATERHOUSE COOPERS LLP AS CURIS' INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM FOR THE YEAR ENDING DECEMBER 31, 2012 IS IN THE BEST INTERESTS OF CURIS AND OUR STOCKHOLDERS AND THEREFORE, RECOMMENDS THAT YOU VOTE "FOR" THIS PROPOSAL.**

### **OTHER MATTERS**

The board knows of no other business that will be presented for consideration at the meeting other than that described above. However, if any other business should come before the meeting, it is the intention of the persons named in the enclosed proxy card to vote, or otherwise act, in accordance with their best judgment on such matters.

### **Stockholder Proposals for 2013 Annual Meeting**

Any proposal that a stockholder of Curis wishes to be considered for inclusion in our proxy statement and proxy for the 2013 annual meeting of stockholders must be submitted to our secretary at our offices, 4 Maguire Road, Lexington, MA 02421, no later than December 22, 2012.

If a stockholder of Curis wishes to present a proposal at the 2013 annual meeting, but does not wish to have the proposal considered for inclusion in our proxy statement and proxy, such stockholder must also give written notice to our secretary at the address noted above. The secretary must receive such notice not less than 60 days nor more than 90 days' prior to the 2013 annual meeting; provided that, in the event that less than 70 days' notice or prior public disclosure of the date of the 2013 annual meeting is given or made, notice by the stockholder must be received not later than the close of business on the 10th day following the date on which such notice of the date of the meeting was mailed or such public disclosure was made, whichever occurs first. The date of our 2013 annual meeting has not yet been established, but assuming it is held on May 30, 2013, in order to comply with the time periods set forth in our by-laws, appropriate notice for the 2013 annual meeting would need to be provided to our secretary no earlier than March 1, 2013, and no later than March 31, 2013. If a stockholder fails to provide timely notice of a proposal to be presented at the 2013 annual meeting, the proxies designated by the board will have discretionary authority to vote on any such proposal.



## **Solicitation of Proxies**

We will bear the costs of soliciting proxies. In addition to solicitations by mail, our directors, officers and regular employees may, without additional remuneration, solicit proxies by telephone, facsimile and personal interviews. We will also request brokerage houses, custodians, nominees and fiduciaries to forward copies of the proxy material to those persons for whom they hold shares and request instructions for voting the proxies. We will reimburse such brokerage houses and other persons for their reasonable expenses in connection with this distribution.

## **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Securities Exchange Act of 1934 requires our directors, executive officers and holders of more than 10% of our common stock to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. Based solely on our review of copies of reports filed by the reporting persons furnished to us, we believe that during the fiscal year ended December 31, 2011, the reporting persons complied with all Section 16(a) filing requirements.

## **Householding of Annual Meeting Materials**

Some banks, brokers and other nominee record holders may be participating in the practice of “householding” proxy statements and annual reports. This means that only one copy of this proxy statement or our 2011 annual report to stockholders may have been sent to multiple stockholders in your household. We will promptly deliver a separate copy of either document if you write or call us at the following address or telephone number: 4 Maguire Road, Lexington, MA 02421, Attention: Secretary, (617) 503-6500. If you want separate copies of the proxy statement and 2011 annual report to stockholders in the future, or if you are receiving multiple copies and would like to receive only one copy for your household, you should contact your bank, broker or other nominee record holder, or you may contact us at the above address or telephone number.

**THE BOARD HOPES THAT STOCKHOLDERS WILL ATTEND THE MEETING. WHETHER OR NOT YOU PLAN TO ATTEND, WE URGE YOU TO VOTE YOUR SHARES OVER THE INTERNET OR BY TELEPHONE, OR COMPLETE, DATE, SIGN AND RETURN THE ENCLOSED PROXY CARD IN THE ACCOMPANYING ENVELOPE. NO POSTAGE NEED BE AFFIXED IF THE PROXY CARD IS MAILED IN THE UNITED STATES. PROMPT RESPONSE WILL GREATLY FACILITATE ARRANGEMENTS FOR THE MEETING AND YOUR COOPERATION IS APPRECIATED. STOCKHOLDERS WHO ATTEND THE MEETING MAY VOTE THEIR STOCK PERSONALLY EVEN THOUGH THEY HAVE VOTED OVER THE INTERNET, BY TELEPHONE OR SENT IN THEIR PROXY CARDS.**

By Order of the Board of Directors,

/s/ Michael P. Gray

Michael P. Gray, Secretary

Lexington, Massachusetts  
April 18, 2012

In both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect our ability to sell our products profitably. Some of these proposed and implemented reforms could result in reduced reimbursement rates for our potential products, which would adversely affect our business strategy, operations and financial results. For example, in March 2010, President Obama signed into law a legislative overhaul of the U.S. healthcare system, known as the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010, which we refer to as the PPACA. This legislation may have far reaching consequences for life science companies like us. As a result of this new legislation, substantial changes could be made to the current system for paying for healthcare in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services, drugs and devices. These structural changes could entail modifications to the existing system of private payors and government programs, such as Medicare and Medicaid, creation of a government-sponsored healthcare insurance source, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the United States could impact the reimbursement for prescribed drugs, biopharmaceuticals and medical devices. If reimbursement for our approved product candidates, if any, is substantially less than we expect in the future, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted. A number of states have challenged the constitutionality of certain provisions of the Health Care Reform Law, and many of these court challenges are still pending final adjudication. Congress has also proposed a number of legislative initiatives, including possible repeal of the PPACA. At this time, it remains unclear whether there will be any changes made to the PPACA, whether to certain provisions or its entirety. In addition, some details regarding the implementation of the PPACA are yet to be determined, and at this time, the full effect that the PPACA would have on our business remains unclear. In addition, the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MPDIMA, reformed the way Medicare will cover and reimburse for pharmaceutical products. This legislation could also decrease the coverage and price that we may receive for our approved product candidates, if any.

The cost-containment measures that healthcare providers are instituting and the results of healthcare reforms such as the PPACA and the MPDIMA may prevent us from maintaining prices for our approved product candidates that are sufficient for us to realize profits and may otherwise significantly harm our business, financial condition and operating results. In addition, to the extent that our approved product candidates, if any, are marketed outside of the United States, foreign government pricing controls and other regulations may prevent us from maintaining prices for such products that are sufficient for us to realize profits and may otherwise significantly harm our business, financial condition and operating results.

## **RISKS RELATED TO OUR COMMON STOCK**

**Our stock price may fluctuate significantly and the market price of our common stock could drop below the price paid.**

The trading price of our common stock has been volatile and is likely to continue to be volatile in the future. For example, our stock traded within a range of a high price of \$5.65 and a low price of \$1.97 per share for the period January 1, 2011 through February 24, 2012. The stock market, particularly in recent years, has experienced significant volatility with respect to pharmaceutical and biotechnology company stocks. Prices for our stock will be determined in the marketplace and may be influenced by many factors, including:

- announcements regarding new technologies by us or our competitors;
- market conditions in the biotechnology and pharmaceutical sectors;
- rumors relating to us or our collaborators or competitors;
- litigation or public concern about the safety of our potential products;
- actual or anticipated variations in our quarterly operating results and any subsequent restatement of such results;

- actual or anticipated changes to our research and development plans;
- deviations in our operating results from the estimates of securities analysts;
- entering into new collaboration agreements or termination of existing collaboration agreements;
- adverse results or delays in clinical trials being conducted by us or any collaborators;
- any intellectual property or other lawsuits involving us;
- third-party sales of large blocks of our common stock;
- sales of our common stock by our executive officers, directors or significant stockholders;
- equity sales by us of our common stock to fund our operations;
- the loss of any of our key scientific or management personnel;
- FDA or international regulatory actions; and
- general economic and market conditions, including recent adverse changes in the domestic and international financial markets.

While we cannot predict the individual effect that these factors may have on the price of our common stock, these factors, either individually or in the aggregate, could result in significant variations in price during any given period of time.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources.

**The limited liquidity for our common stock could affect an investor's ability to sell our shares at a satisfactory price and makes the trading price of our common stock more volatile.**

Our common stock is relatively illiquid. As of December 31, 2011, we had approximately 77.1 million shares of common stock outstanding. The average daily trading volume in our common stock during the prior 90 trading days ending on December 31, 2011 was approximately 383,000 shares. A more active public market for our common stock may not develop, which would continue to adversely affect the trading price and liquidity of our common stock. Moreover, common stock with a thin trading market may experience greater price fluctuation than the stock market as a whole. Without a large float, our common stock is less liquid than the stock of companies with broader public ownership and, as a result, the trading prices of our common stock may be more volatile.

**Future sales of shares of our common stock, including shares issued upon the exercise of currently outstanding options and warrants or pursuant to our universal shelf registration statement could result in dilution to our stockholders and negatively affect our stock price.**

Most of our outstanding common stock can be traded without restriction at any time. As such, sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell such shares, could reduce the market price of our common stock. In addition, we have a significant number of shares that are subject to outstanding options and warrants and in the future we may issue additional options, warrants or other derivative securities convertible into our common stock. The exercise of any such options, warrants or other derivative securities, and the subsequent sale of the underlying common stock could cause a further decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

Furthermore, as of December 31, 2011, we have outstanding warrants to purchase 1,610,818 shares of our common stock that contain antidilution adjustment provisions that will result in a decrease in the price and an increase in the number of shares of common stock issuable upon exercise of such warrants in the event of certain issuances of common stock by us at prices below \$3.55 per share. For example, assuming that we issued and sold shares of common stock in a public offering at \$3.00 per share, these warrants would become exercisable for an aggregate of 1,630,532 shares of our common stock, at an exercise price of \$3.51 per share, which is equal to an aggregate of additional 19,714 shares as a result of the adjustment. To the extent that we are required to adjust the price and number of shares underlying these warrants as a result of this antidilution clause, and thereafter such warrants are exercised, additional shares of our common stock will be issued that will be eligible for resale in the public market, which could result in added dilution to our security holders and could also have an adverse effect on the market price of our common stock.

We currently have on file with the SEC a “universal” shelf registration statement which allows us to offer and sell registered common stock, preferred stock and warrants from time to time pursuant to one or more offerings at prices and terms to be determined at the time of sale. For example, in June 2011 we entered into an agreement with MLV pursuant to which, from time to time, we may offer and sell up to \$20 million of the common stock that was registered on this shelf registration statement through MLV pursuant to one or more “at the market” offerings. In addition, with our prior written approval, MLV may also sell these shares of common stock by any other method permitted by law, including in privately negotiated transactions. Sales of substantial amounts of shares of our common stock or other securities under this registration statement could lower the market price of our common stock and impair our ability to raise capital through the sale of equity securities.

**Compliance with Section 404 of the Sarbanes-Oxley Act of 2002 requires our management to devote substantial time to compliance initiatives, and if our independent registered public accounting firm is required to provide an attestation report on our internal controls but is unable to provide an unqualified attestation report, our stock price could be adversely affected.**

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on the effectiveness of our internal control over financial reporting. The internal control report must contain (i) a statement of management’s responsibility for establishing and maintaining adequate internal control over financial reporting, (ii) a statement identifying the framework used by management to conduct the required evaluation of the effectiveness of our internal control over financial reporting and (iii) management’s assessment of the effectiveness of our internal control over financial reporting as of the end of our most recent fiscal year, including a statement as to whether or not internal control over financial reporting is effective.

To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, hire additional employees for our finance and audit functions, potentially engage outside consultants and adopt a detailed work plan to (i) assess and document the adequacy of internal control over financial reporting, (ii) continue steps to improve control processes where appropriate, (iii) validate through testing that controls are functioning as documented, and (iv) implement a continuous reporting and improvement process for internal control over financial reporting. In addition, in connection with the attestation process by our independent registered public accounting firm, if required, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation. If we cannot favorably assess the effectiveness of our internal control over financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified attestation report on our internal controls, investors could lose confidence in our financial information and our stock price could decline.

**If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline.**

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. There are currently nine research analysts that publish research coverage related to Curis. These securities and industry analysts may not maintain such coverage or we may fail to obtain research coverage by additional securities and industry analysts. If we do not maintain such existing coverage, and additional securities or industry analysts do not commence coverage of our company, the trading price for our stock may be negatively impacted. If one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

**We do not intend to pay dividends on our common stock, and any return to investors will come, if at all, only from potential increases in the price of our common stock.**

At the present time, we intend to use available funds to finance our operations. Accordingly, while payment of dividends rests within the discretion of our board of directors, no common stock dividends have been declared or paid by us and we have no intention of paying any common stock dividends in the foreseeable future.

**Insiders have substantial influence over us and could delay or prevent a change in corporate control.**

As of December 31, 2011, we believe that our directors, executive officers and principal stockholders, together with their affiliates, owned, in the aggregate, approximately 31% of our outstanding common stock. As a result, these stockholders, if acting together, will be able to exert influence over the management and affairs of our company and over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership could harm the market price of our common stock by:

- delaying, deferring or preventing a change in control of our company;
- impeding a merger, consolidation, takeover or other business combination involving our company; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

**We have anti-takeover defenses that could delay or prevent an acquisition that our stockholders may consider favorable and the market price of our common stock may be lower as a result.**

Provisions of our certificate of incorporation, our bylaws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing changes in control of our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interest. For example, we have divided our board of directors into three classes that serve staggered three-year terms, we may issue shares of our authorized “blank check” preferred stock and our stockholders are limited in their ability to call special stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. These provisions could discourage, delay or prevent a change in control transaction.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

We currently lease a facility for our administrative, research and development requirements located at 4 Maguire Road in Lexington, Massachusetts consisting of 24,529 square feet pursuant to a lease that expires February 2018. We believe that our existing facility will be suitable and adequate to meet our needs for the foreseeable future.

**ITEM 3. LEGAL PROCEEDINGS**

We are currently not a party to any material legal proceedings.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDERS MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

(a) *Market Information.* Our common stock is traded on the NASDAQ Global Market under the trading symbol "CRIS." The following table sets forth, for the fiscal periods indicated, the high and low sales prices per share of our common stock as reported on the NASDAQ Global Market:

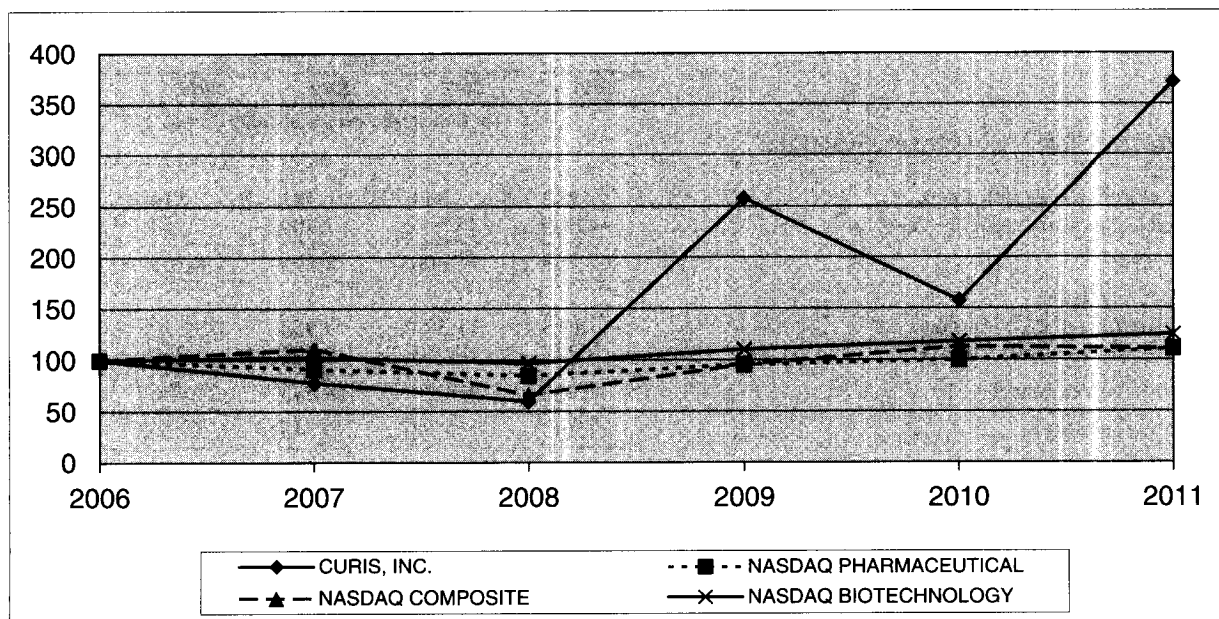
	Curis Common Stock	
	High	Low
<b><u>Year ended December 31, 2010</u></b>		
First Quarter .....	\$3.70	\$2.05
Second Quarter .....	\$3.58	\$1.38
Third Quarter .....	\$1.87	\$1.21
Fourth Quarter .....	\$2.14	\$1.28
<b><u>Year ended December 31, 2011</u></b>		
First Quarter .....	\$3.63	\$1.97
Second Quarter .....	\$4.42	\$3.00
Third Quarter .....	\$4.30	\$2.70
Fourth Quarter .....	\$4.72	\$2.87

(b) *Holders.* On February 24, 2012, the last reported sale price of our common stock on the NASDAQ Global Market was \$4.50 and there were 268 holders of record of our common stock. The number of record holders may not be representative of the number of beneficial owners because many of the shares of our common stock are held by depositories, brokers or other nominees.

(c) *Dividends.* We have never declared or paid any cash dividends on our common stock. We currently intend to retain earnings, if any, to support our business strategy and do not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the sole discretion of our board of directors after taking into account various factors, including our financial condition, operating results, capital requirements and any plans for expansion.

(d) *Issuer Purchases of Equity Securities.* We did not make any purchases of our shares of common stock in 2011.

(e) *Performance Graph.* The graph below compares the cumulative total stockholder return on our common stock for the period from December 31, 2006 through December 31, 2011, with the cumulative total return on (i) NASDAQ Pharmaceutical Index , (ii) NASDAQ Composite Index and (iii) NASDAQ Biotechnology Index. The comparison assumes investment of \$100 on December 31, 2006 in our common stock and in each of the indices and, in each case, assumes reinvestment of all dividends.



	12/31/06	12/31/07	12/31/08	12/31/09	12/31/10	12/31/11
CURIS INC. ....	100.00	77.78	59.52	257.94	157.14	371.43
NASDAQ COMPOSITE INDEX ....	100.00	110.26	65.65	95.19	112.10	110.81
NASDAQ PHARMACEUTICAL INDEX ....	100.00	90.99	84.71	95.64	100.10	110.44
NASDAQ BIOTECHNOLOGY INDEX ....	100.00	102.53	96.57	110.05	117.19	124.54



## ITEM 6. SELECTED FINANCIAL DATA

The selected consolidated financial data set forth below have been derived from our consolidated financial statements. These historical results are not necessarily indicative of results to be expected for any future period. You should read the data set forth below in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the consolidated financial statements and related notes included elsewhere in this report.

	Year Ended December 31,				
	2011	2010	2009	2008	2007
	(in thousands, except per share data)				
<b>Consolidated Statement of Operations Data:</b>					
Revenues:					
Research and development .....	\$ 463	\$ 344	\$ 781	\$ 514	\$ 3,262
License and maintenance fees(1) .....	14,300	15,656	7,809	7,853	13,127
Net revenues .....	14,763	16,000	8,590	8,367	16,389
Costs and expenses:					
Research and development .....	13,693	11,373	9,933	13,226	14,779
General and administrative .....	8,273	10,265	8,702	8,260	9,984
Total costs and expenses .....	21,966	21,638	18,635	21,486	24,763
Loss from operations .....	(7,203)	(5,638)	(10,045)	(13,119)	(8,374)
Other income (expense):					
Interest and other income .....	100	627	222	1,000	1,495
Change in fair value of warrants .....	(2,756)	576	—	—	—
Interest expense .....	—	—	—	(4)	(85)
Total other income, net .....	(2,656)	1,203	222	996	1,410
Net loss .....	\$ (9,859)	\$ (4,435)	\$ (9,823)	\$ (12,123)	\$ (6,964)
Basic and diluted net loss per common share .....	\$ (0.13)	\$ (0.06)	\$ (0.15)	\$ (0.19)	\$ (0.13)
Weighted average common shares (basic and diluted) .....					
	76,352	74,959	65,061	63,378	54,915

	(in thousands) As of December 31,				
	2011	2010	2009	2008	2007
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and marketable securities .....	\$ 37,718	\$ 40,380	\$ 25,035	\$ 28,853	\$ 41,459
Working capital .....	34,717	37,608	23,347	26,748	35,410
Investment—restricted .....	236	497	216	210	210
Total assets .....	48,180	50,649	36,099	39,982	53,817
Long-term obligations (2) .....	4,518	1,656	—	—	404
Accumulated deficit .....	(732,088)	(722,229)	(717,793)	(707,971)	(695,848)
Total stockholders’ equity .....	39,876	45,518	33,052	37,225	46,845

- (1) During the years ended December 31, 2011, 2009 and 2008, we recognized \$14,000,000, \$6,000,000 and \$6,000,000 of revenue for contingent cash payments that we earned during each of 2011, 2009 and 2008, respectively, under our June 2003 Hedgehog pathway inhibitor collaboration with Genentech. During the year ended December 31, 2007, we recognized \$10,509,000 of revenue under this collaboration, which included \$7,509,000 in previously deferred revenue and \$3,000,000 for a contingent cash payment that we earned during 2007. During the year ended December 31, 2010, we recognized \$11,000,000 of revenue for contingent cash payments that we earned under our August 2009 license agreement with Debiopharm, and we also recognized \$4,000,000 in settlement proceeds from Micromet pursuant to the settlement agreement that we entered into in February 2010 to resolve a contract claim we filed related to our June 2001 agreement with Micromet.
- (2) Long-term obligations for the years ended December 31, 2011 and 2010 are comprised of a warrant liability established as part of our January 2010 registered direct offering of \$4,361,000 and \$1,605,000, respectively, with the remainder related to deferred rent payments. Long-term obligations for the year ended December 31, 2007 related to long-term debt payments.

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis of financial condition and results of operations should be read together with "Selected Financial Data," and our financial statements and accompanying notes appearing elsewhere in this annual report on Form 10-K. This discussion contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth under Item 1A, "Risk Factors" and elsewhere in this report.*

### Overview

We are a drug discovery and development company that is committed to leveraging our innovative signaling pathway drug technologies in seeking to develop next generation network-targeted cancer therapies. We are building upon our experience in modulating signaling pathways, including the Hedgehog signaling pathway, in our effort to develop network-targeted cancer therapies. We conduct our research and development programs both internally and through strategic collaborations.

#### ***Hedgehog Pathway Inhibitor Program (Erivedge™)***

*Erivedge™ (vismodegib) capsule.* Our most advanced program is our Hedgehog pathway inhibitor program under collaboration with Genentech, Inc., a member of the Roche Group. The lead drug candidate being developed under this program is Erivedge, a first-in-class orally-administered small molecule Hedgehog pathway inhibitor, which is also referred to as vismodegib, GDC-0449 and RG3616. Erivedge is designed to selectively inhibit signaling in the Hedgehog pathway by targeting a protein called Smoothened. The Hedgehog signaling pathway plays an important role in regulating proper growth and development in the early stages of life and becomes less active in adults. However, mutations in the pathway that reactivate Hedgehog signaling are seen in certain cancers, including basal cell carcinoma, or BCC. Abnormal signaling in the Hedgehog pathway is implicated in over 90% of BCC cases.

In January 2012, Erivedge was approved by the U.S. Food and Drug Administration, or FDA, as the first and only FDA-approved medicine for adults with advanced forms of basal cell carcinoma that has spread to other parts of the body or that has come back after surgery or that their healthcare provider decides cannot be treated with surgery or radiation. It is not known if Erivedge is safe and effective in children. We earned a \$10,000,000 milestone payment from Genentech as a result of the FDA's approval of Erivedge in this indication and we are also entitled to receive royalties on future sales of the product. During the fourth quarter of 2011, we received a total of \$14,000,000 in milestone payments from Genentech relating to the FDA's acceptance of Genentech's New Drug Application, or NDA, for Erivedge and the European Medicines Agency's, or EMA's, acceptance for review of a Marketing Authorization Application, or MAA for Erivedge, that was submitted by Roche in December 2011. The Genentech NDA and Roche MAA applications were based on positive clinical data from ERIVANCE BCC/SHH4476g, a pivotal phase II study of Erivedge in patients with advanced BCC. We will receive an additional milestone payment if Erivedge also receives EMA marketing authorization, as well as royalties on any future sales in this territory.

Genentech is also conducting a separate phase II clinical trial of Erivedge in patients with operable nodular basal cell carcinoma, which is a less severe form of the disease and accounts for a significant percentage of the approximately two million BCCs diagnosed annually in the United States. We anticipate that the study will be completed during early 2013.

In addition to the BCC clinical trials being conducted directly by Genentech and Roche, Erivedge is also currently being tested in other cancers in trials under collaborative agreements between Genentech and either third-party investigators or the U.S. National Cancer Institute, or NCI.

### ***Network-Targeted Cancer Programs***

Our internal drug development efforts are focused on our network-targeted cancer programs, in which we are seeking to design single novel small molecule drug candidates that inhibit multiple signaling pathways that are believed to play roles in cancer cell proliferation. We refer to this approach as cancer network disruption. We believe that our approach of targeting multiple nodes in cancer signaling pathway networks may provide a better therapeutic effect than many of the cancer drugs currently marketed or in development since our drug candidates are being designed to disrupt multiple targets in the cancer network environment as compared to most other cancer drugs which are designed to disrupt only one target.

**CUDC-101.** Our lead candidate from these programs is CUDC-101, a first-in-class small molecule compound designed to simultaneously target histone deacetylase, or HDAC, epidermal growth factor receptor, or EGFR, and human epidermal growth factor receptor 2, or HER2, all of which are validated cancer targets. A significant amount of our capital resources are focused on the ongoing clinical development of this molecule. To date, we have completed a phase I dose escalation clinical trial of CUDC-101 in 25 patients with advanced, refractory solid tumors and we have completed enrollment in a phase I expansion trial to test CUDC-101 in 46 patients with specific tumor types, including breast, gastric, head and neck, liver and non-small cell lung cancers. The phase I expansion trial is designed as an open-label study in which patients are treated with CUDC-101 at the maximum tolerated dose, which was determined in the phase I dose escalation study to be 275 milligrams per meter<sup>2</sup>. The primary objectives of this study are to compare the safety and tolerability of CUDC-101 in subjects with these specific advanced solid tumors when the drug is administered via one-hour intravenous infusion either on a five days per week schedule (one week on/one week off) or on a three days per week schedule (three weeks on/one week off).

During the second quarter of 2011, we initiated a phase I clinical trial of CUDC-101 in locally advanced head and neck cancer patients whose cancer is human papilloma virus, or HPV, negative. We have treated four patients in this trial as of February 24, 2012. The primary objectives of this study are to evaluate the safety and tolerability of CUDC-101 when administered in combination with the current standard-of-care of cisplatin, a chemotherapeutic drug, and radiation. Upon determination of the maximum tolerated dose and assuming the otherwise successful completion of the phase I trial, we intend to conduct a randomized phase II two-arm clinical trial in which head and neck cancer patients will receive cisplatin and radiation plus or minus CUDC-101. The phase II study would seek to evaluate whether the addition of CUDC-101 can improve the efficacy of cisplatin and radiation therapy in this patient population. We currently estimate initiating this phase II study in the first half of 2013.

We are also working on an oral formulation of CUDC-101, which we believe has the potential to make CUDC-101 more competitive in certain cancers such as non-small cell lung cancer or in other cancers where there are investigational or competing commercially available molecules that are orally administered. Pending the successful completion of ongoing formulation and preclinical development work, we intend to begin a phase I study of an oral formulation of CUDC-101 in the second half of 2012.

**CUDC-907.** In January 2011, we selected development candidate CUDC-907, an orally bioavailable, network-targeted small molecule that is designed to inhibit HDAC and phosphatidylinositol-3-kinase, or PI3K. Our scientists are developing CUDC-907 based on published and internally generated data demonstrating that HDAC and PI3K inhibitors have synergistic interaction in certain preclinical cancer models. We believe that this synergistic mechanism of cancer signaling network disruption, which demonstrated efficacy and a favorable safety profile in a number of preclinical xenograft models, could translate into clinical advantages over single agents.

In November 2011, we entered into an agreement under which The Leukemia & Lymphoma Society, or LLS, will provide a portion of the funding of the development of CUDC-907 if we succeed in advancing this development candidate into a clinical trial for patients with B-cell lymphoma and multiple myeloma. Pending the successful completion of ongoing formulation and preclinical development work, we expect to file an IND with the FDA to test an oral formulation of CUDC-907 during the second half of 2012.

In addition to our development-stage programs, we continue to progress additional proprietary preclinical research programs and expect that we will select additional small molecule inhibitors from our preclinical portfolio in the future.

### ***Hsp90 Program***

***Debio 0932.*** Our heat shock protein 90, or Hsp90, program is being developed by Debiopharm, a Swiss pharmaceutical development company, under an August 2009 license agreement between Curis and Debiopharm. The lead molecule under this license collaboration was designated Debio 0932 by Debiopharm. In April 2010, Debiopharm treated the first patient in a phase I clinical trial to evaluate the safety of Debio 0932 in patients suffering from advanced solid tumors. In 2011, Debiopharm successfully advanced Debio 0932 through the dose escalation portion of the phase I study. Debio 0932 was generally well tolerated, with no evidence of ocular or liver toxicity, and showed promising signs of efficacy in patients with advanced solid tumors in this study. Debiopharm has indicated that it expects to present phase I data from this phase I study at a medical conference during the first half of 2012.

Debiopharm advanced Debio 0932 into the phase Ib expansion portion of the study in the beginning of 2012. Debiopharm expects to treat approximately 30 patients in this study, with the primary objectives of the phase Ib study, an expansion cohort of solid tumor patients, will be to further assess the safety profile, pharmacokinetics and pharmacodynamics of Debio 0932 at the recommended dose level of 1000mg daily that was established in the dose escalation portion of the Phase I clinical trial, and to make a preliminary assessment of anti-tumor activity in patients with advanced solid tumors, including patients with non-small cell lung cancer.

Debiopharm has also indicated that it expects to initiate a combination Phase I/II study in non-small cell lung cancer patients in the second quarter of 2012. We are eligible for our next milestone payment under our license agreement if and when Debiopharm treats its fifth patient in a phase II clinical trial, assuming that Debiopharm advances Debio 0932 into phase II clinical testing. We currently anticipate that phase II testing could commence in the first half of 2013.

### ***Liquidity***

Since our inception, we have funded our operations primarily through license fees, contingent cash payments, research and development funding from our corporate collaborators, the private and public placement of our equity securities, debt financings and the monetization of certain royalty rights. We have never been profitable and have an accumulated deficit of \$732,088,000 as of December 31, 2011. We expect to incur significant operating losses for the next several years as we devote substantially all of our resources to our research and development programs. We will need to generate significant revenues to achieve profitability and do not expect to achieve profitability in the foreseeable future, if at all. We anticipate that existing capital resources as of December 31, 2011 should enable us to maintain current and planned operations into the second half of 2013. We believe that near term key drivers to our success will include:

- Genentech's ability to successfully launch and commercialize Erivedge in the US;
- Genentech's receipt of EMA approval to commercialize Erivedge in advanced BCC as well as its ability to successfully launch and commercialize Erivedge in the European market;
- Debiopharm's ability to advance Debio 0932 into later stages of clinical development;
- our ability to successfully plan, finance and complete clinical trials for CUDC-101 and advance CUDC-101 into later stages of clinical development in indications other than head and neck cancers;
- our ability to successfully advance early-stage development candidates, such as CUDC-907 into clinical testing;
- our ability to successfully enter into one or more material licenses or collaboration agreements for our proprietary drug candidates; and
- our ability to advance the research of other small molecule cancer drug candidates that we are developing under our proprietary pipeline of network-targeted cancer programs.

In the longer term, a key driver to our success will be our ability, and the ability of any current or future collaborator or licensee, to successfully commercialize drugs based upon our proprietary technologies.

#### *Collaboration Agreements*

We are currently a party to a June 2003 collaboration with Genentech relating to our Hedgehog pathway inhibitor technologies, and an August 2009 license agreement with Debiopharm relating to our Hsp90 inhibitor technology. Our past and current collaborations have generally provided for research, development and commercialization programs to be wholly or majority-funded by our collaborators and provide us with the opportunity to receive additional contingent cash payments if specified development and regulatory approval objectives are achieved, as well as royalty payments upon the successful commercialization of any products based upon the collaborations. We are currently not receiving any research funding and we do not expect to receive such funding in the future from Genentech or Debiopharm under our current agreements with these parties. Under our collaborations with Genentech, we currently expect to incur only costs related to the maintenance of licenses, including sublicense payments due upon milestone payments and any royalties we receive, as well as patent-related expenses. As a result of our licensing agreements with various universities, we are also obligated to make payments to these university licensors when we receive certain payments from Genentech. As of December 31, 2011, we have incurred an aggregate of approximately \$1,640,000 related to ongoing agreements, of which \$1,600,000 relates to payments that we received from Genentech. As we receive additional milestone payments from Genentech upon FDA approval of Erivedge obtained in January 2012, and EMA approval, if achieved, we will be obligated to pay 5% in additional sublicense fees to these licensors, as well as a total of 5% of any royalties received from the sale of Erivedge. We do not expect to incur any material costs related to our Hsp90 technologies under development by Debiopharm under our August 2009 license agreement with Debiopharm.

Our current collaboration agreements are summarized as follows:

*Genentech Hedgehog Pathway Inhibitor Collaboration.* Under the terms of the June 2003 agreement with Genentech, we granted Genentech an exclusive, global, royalty-bearing license, with the right to sublicense, to make, use, sell and import small molecule and antibody Hedgehog pathway inhibitors. In November 2008, Genentech granted a sublicense to F. Hoffmann-LaRoche, Ltd (Roche) for non-U.S. rights to GDC-0449. Roche received this sublicense pursuant to an agreement between Genentech and Roche under which Genentech granted Roche an option to obtain a license to commercialize certain Genentech products in non-U.S. markets. In February 2010, we announced that Chugai Pharmaceutical Co., Ltd. had exercised its right of first refusal for the development and commercialization in Japan of GDC-0449 under an existing agreement with Roche. Genentech and Roche have primary responsibility for worldwide clinical development, regulatory affairs, manufacturing and supply, formulation and sales and marketing. We are not a party to this agreement between Genentech and Roche but we are eligible to receive cash payments for regulatory filing and approval objectives achieved and future royalties on products developed outside of the U.S., if any, under our June 2003 collaboration agreement with Genentech.

The lead drug candidate being developed under this program is Erivedge, a first-in-class orally-administered small molecule Hedgehog pathway inhibitor that is the first and only FDA-approved medicine for adults with advanced forms of basal cell carcinoma. Genentech and Roche are responsible for worldwide clinical development, regulatory affairs, manufacturing and supply, formulation and sales and marketing of Erivedge. We are eligible to receive cash payments for regulatory filing and approval objectives achieved and future royalties on products developed outside of the U.S., if any, under our June 2003 collaboration agreement with Genentech. We are eligible to receive up to \$115,000,000 in contingent cash payments under the terms of our June 2003 collaboration for the development of Erivedge or another small molecule, assuming the successful achievement by Genentech and Roche of specified clinical development and regulatory objectives. We have received \$42,000,000 of this amount including the \$10,000,000 payment that we earned in January 2012. We are also eligible to receive royalties on sales of any Hedgehog pathway inhibitor products that are successfully commercialized by Genentech and Roche. For Erivedge, we are entitled to a mid-to-high single digit royalty, which escalates within this range with increasing product sales. In certain specified circumstances, the royalty rate applicable to Erivedge may be decreased to a low-to-mid single digit royalty.

*Debiopharm Hsp90 Collaboration.* In August 2009, we granted a worldwide, exclusive royalty-bearing license to our Hsp90 inhibitor technology to Debiopharm, a Swiss pharmaceutical development company. The lead molecule under this license collaboration was designated Debio 0932 by Debiopharm. Debiopharm has assumed all future development responsibility and costs related to the development, registration and commercialization of products under the agreement. As part of the consideration under the agreement, Debiopharm paid us an up-front license fee of \$2,000,000, and we received \$11,000,000 during 2010 in contingent payments upon Debiopharm's successful achievement of clinical objectives, including the approval from French regulatory authorities of Debiopharm's clinical trial application, or CTA, to begin phase I clinical trials and the treatment of the fifth patient in this trial. We are also eligible to receive royalties if any products under the license agreement are successfully developed and commercialized. For net sales of Debio 0932 that are made directly by Debiopharm, we are entitled to a high single digit to low double digit royalty, which escalates within this range with increasing product sales. In certain specified circumstances, the royalty rate applicable to Debio 0932 may be reduced. We believe that it is more likely that Debiopharm will sublicense Debio 0932 following its further development, and in this case we are entitled to a share of royalties that Debiopharm receives from such sublicensee.

### **Financial Operations Overview**

*General.* Our future operating results will largely depend on the magnitude of payments from our current and potential future corporate collaborators and the progress of drug candidates currently in our research and development pipeline. The results of our operations will vary significantly from year to year and quarter to quarter and depend on, among other factors, the timing of our entry into new collaborations, if any, the timing of the receipt of payments, if any, from new or existing collaborators and the cost and outcome of any preclinical development or clinical trials then being conducted. We anticipate that existing capital resources as of December 31, 2011 should enable us to maintain current and planned operations into the second half of 2013. Our ability to continue funding our planned operations into and beyond the second half of 2013 is dependent on future contingent payments that we may receive from Debiopharm, Genentech, or the LLS upon the achievement of development and regulatory approval objectives, our ability to manage our expenses and our ability to raise additional funds through additional corporate collaborations, equity or debt financings, or from other sources of financing.

We expect to end 2012 with cash, cash equivalents and marketable securities of \$23 million to \$27 million, excluding any potential payments from existing or new collaborators. We expect that our expenses associated with the clinical development of CUDC-101 will increase as we continue to treat patients in our phase I trial in head and neck cancers and initiation of additional trials for CUDC-101 and CUDC-907, resulting in an increase in our research and development expenses for future periods as compared to prior years. We expect that research and development expenses for the year ended December 31, 2012 will be \$16 million to \$20 million and that general and administrative expenses will be \$10 million to \$12 million. These expense estimates include \$800,000 and \$2.5 million of stock-based compensation expense for research and development and general and administrative expense, respectively, which includes employee and director equity grants issued in January 2012. Actual stock-based compensation expense for fiscal 2012 may be higher as the result of our issuance of additional awards as part of our planned compensation programs, consistent with past practices.

*Revenue.* We do not expect to generate any revenue from our direct sale of products for several years, if ever. Substantially all of our revenues to date have been derived from license fees, research and development payments, and other amounts that we have received from our strategic collaborators and licensees. For the year ended December 31, 2011, Genentech accounted for \$14,388,000, or 97%, of our total revenue. We have not recognized any royalty revenue to date but we expect that we will recognize royalties attributed to the sale of Erivedge in 2012.

We could receive additional milestone payments from our collaborators Genentech and Debiopharm, provided the respective programs meet contractually-specified development and regulatory objectives. For example, we earned a \$10,000,000 milestone payment from Genentech in January 2012 upon FDA approval of Erivedge. In addition, Erivedge is currently being reviewed for potential marketing approval by the EMA in European territories. We are eligible to receive additional milestone revenue should Erivedge receive approval by the EMA, and we are also eligible to receive royalties on net sales of Erivedge.

We currently receive no research funding for our programs under our collaborations with Genentech and Debiopharm and we do not expect to receive such funding in the future under these collaborations. Accordingly, our only source of revenues and/or cash flows from operations for the foreseeable future will be up-front license payments and funded research and development that we may receive under new collaboration agreements, if any, contingent cash payments for the achievement of clinical development and regulatory objectives, if any are met, under new collaborations or our existing collaborations with Genentech and Debiopharm and royalty payments that are contingent upon the successful commercialization of any products based upon these collaborations. Our ability to enter into new collaborations and our receipt of additional payments under our existing collaborations with Genentech and Debiopharm cannot be assured, nor can we predict the timing of any such arrangements or payments, as the case may be.

**Research and Development.** Research and development expense consists of costs incurred to discover, research and develop our drug candidates. These expenses consist primarily of: (1) salaries and related expenses for personnel including stock-based compensation expense; (2) outside service costs including clinical research organizations, medicinal chemistry and sublicense payments; and (3) the costs of supplies and reagents, consulting, and occupancy and depreciation charges. We expense research and development costs as incurred. We are currently incurring only nominal research and development expenses under our Hedgehog pathway inhibitor collaboration with Genentech related to the maintenance of third-party licenses to certain background technologies. For each contingent payment, if any, received under the Hedgehog pathway inhibitor collaboration, we would be obligated to make payments to certain third-party licensors and recognize the related expense.

Our research and development programs, both internal and under collaboration, are summarized in the following table:

<b>Product Candidate</b>	<b>Primary Disease</b>	<b>Collaborator/Licensee</b>	<b>Status</b>
<b><i>Hedgehog Pathway Inhibitor</i></b>			
- Erivedge (vismodegib)	Advanced BCC	Genentech	FDA approval
	Advanced BCC	Genentech	MAA review
- Erivedge (vismodegib)	Operable Nodular BCC	Genentech	Phase II
<b><i>Network-targeted Cancer Programs</i></b>			
- CUDC-101 intravenous formulation (HDAC, EGFR, Her2 inhibitor)	Cancer	Internal development	Phase I expansion
- CUDC-101 intravenous formulation (HDAC, EGFR, Her2 inhibitor)	Locally advanced HPV-head and neck cancer	Internal development	Phase I
- CUDC-101 oral formulation (HDAC, EGFR, Her2 inhibitor)	Cancer	Internal development	Development candidate
- CUDC-907 (HDAC, PI3K inhibitor)	Cancer	Internal development	Development candidate
- Other network-targeted cancer programs	Cancer	Internal development	Preclinical
- Debio 0932 (formerly CUDC-305) (Hsp90 inhibitor)	Cancer	Debiopharm	Phase Ib

In the chart above, “FDA approval” means that Genentech’s NDA was approved by the FDA for commercialization of Erivedge in the United States. “MAA review” means that Roche has filed an MAA with the EMA, and the EMA has accepted and is currently reviewing the application for potential approval to commercialize Erivedge in Europe. “Phase II” means that Genentech is currently treating human patients in a phase II clinical trial, the primary objective of which is a therapeutic response in the patient population. “Phase I expansion” means that we are currently treating human patients with specific tumor types in an extension of our phase I dose escalation trial, at the maximum tolerated dose from such trial, the principal purpose of which is to evaluate the safety and tolerability of the compound being tested. “Phase Ib” means that Debiopharm is further assessing the safety profile, pharmacokinetics and pharmacodynamics of Debio 0932 at the recommended phase II dose level, and seeking to make a preliminary assessment of anti-tumor activity in patients with advanced solid tumors. “Phase I” means that we are currently treating human patients in separate phase I clinical trials with CUDC-101, the principal purpose of which is to evaluate the safety and tolerability of the compound being tested. “Development candidate” means that we have selected a single lead candidate for potential future clinical

development and are seeking to complete the relevant safety, toxicology, and other studies required to submit an IND application with the FDA seeking to commence a phase I clinical trial based on our testing in several preclinical models of human disease of various compounds from a particular compound class. “Preclinical” means that we are seeking to obtain evidence of therapeutic efficacy and safety in preclinical models of human disease of one or more compounds within a particular class of drug candidates.

Because of the early stages of development of these programs, our ability and that of our collaborators and licensees to successfully complete preclinical studies and clinical trials of these drug candidates, and the timing of completion of such programs, is highly uncertain. There are numerous risks and uncertainties associated with developing drugs which may affect our and our collaborators’ future results, including:

- the scope, quality of data, rate of progress and cost of clinical trials and other research and development activities undertaken by us or our collaborators;
- the results of future preclinical studies and clinical trials;
- the cost and timing of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our drug candidates and any products that we may develop;
- the effect of competing technological and market developments; and
- the cost and effectiveness of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

We cannot reasonably estimate or know the nature, timing and estimated costs of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from any of our drug candidates. Any failure to complete the development of our drug candidates in a timely manner could have a material adverse effect on our operations, financial position and liquidity.

A further discussion of some of the risks and uncertainties associated with completing our research and development programs on schedule, or at all, and some consequences of failing to do so, are set forth above in “Part I, Item 1A—Risk Factors.”

*General and Administrative.* General and administrative expense consists primarily of salaries, stock-based compensation expense and other related costs for personnel in executive, finance, accounting, business development, legal, information technology, corporate communications and human resource functions. Other costs include facility costs not otherwise included in research and development expense, insurance, and professional fees for legal, patent and accounting services. Patent costs include certain patents covered under collaborations, a portion of which is reimbursed by collaborators and a portion of which is borne by us. We expect that our general and administration expenses will increase in future periods as patent costs related to our Hedgehog pathway inhibitor collaboration with Genentech increase as well as an increase in our non-cash stock-based compensation expense in 2012 as compared to prior periods.

### **Critical Accounting Policies and Estimates**

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the United States requires that we make estimates and assumptions that affect the reported amounts and disclosure of certain assets and liabilities at our balance sheet date. Such estimates and judgments include the carrying value of property and equipment and intangible assets, revenue recognition, the value of certain liabilities, including our warrant liability, and stock-based compensation. We base our estimates on historical experience and on various other factors that we believe to be appropriate under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.



While our significant accounting policies are more fully described in our consolidated financial statements, we believe that the following accounting policies are critical to understanding the judgments and estimates we use in preparing our financial statements:

### ***Revenue Recognition***

Our business strategy includes entering into collaborative license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of our product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of clinical development milestones and royalties on product sales. We follow the provisions of the Financial Accounting Standards Board, or FASB, Codification Topic 605, *Revenue Recognition*.

#### ***License Fees and Multiple Element Arrangements.***

In January 2010, we adopted a new U.S. GAAP accounting standard which amends existing revenue recognition accounting guidance to provide accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This new guidance eliminates the requirement to establish objective evidence of fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no vendor-specific objective evidence or third-party evidence to determine the fair value of that undelivered item. Because we did not enter into any new multiple element arrangements or modify our existing collaborations during the year ended December 31, 2011, recognition models used to derive our revenues for the year ended December 31, 2011 reflect the superseded guidance and the adoption of the new standard will be implemented on a prospective basis for new or materially modified arrangements.

For multiple element arrangements, including license agreements, entered into prior to January 1, 2010, guidance required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. Under this guidance, if the fair value of all of the undelivered elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined.

Non-refundable license fees are recognized as revenue when we have a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and we have no further performance obligations under the license agreement. Multiple element arrangements, such as license and development arrangements are analyzed to determine whether the deliverables, which often include a license and performance obligations such as research and steering committee services, can be separated or whether they must be accounted for as a single unit of accounting in accordance with U.S. generally accepted accounting principles, or GAAP. We recognize up-front license payments as revenue upon delivery of the license only if the license has stand-alone value and the fair value of the undelivered performance obligations, typically including research and/or steering committee services, can be determined. If the fair value of the undelivered performance obligations can be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have stand-alone value or (ii) have stand-alone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting and the license payments and payments for performance obligations are recognized as revenue over the estimated period of when the performance obligations are performed.

Whenever we determine that an arrangement should be accounted for as a single unit of accounting, we must determine the period over which the performance obligations will be performed and revenue will be recognized. Revenue will be recognized using either a relative performance or straight-line method. We recognize revenue using the relative performance method provided that we can reasonably estimate the level of

effort required to complete our performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Direct labor hours or full-time equivalents are typically used as the measure of performance. Revenue recognized under the relative performance method would be determined by multiplying the total payments under the contract, excluding royalties and payments contingent upon achievement of substantive milestones, by the ratio of level of effort incurred to date to estimated total level of effort required to complete our performance obligations under the arrangement. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the relative performance method, as of each reporting period.

If we cannot reasonably estimate the level of effort required to complete our performance obligations under an arrangement, the performance obligations are provided on a best-efforts basis and we can reasonably estimate when the performance obligation ceases or becomes inconsequential, then the total payments under the arrangement, excluding royalties and payments contingent upon achievement of substantive milestones, would be recognized as revenue on a straight-line basis over the period we expect to complete our performance obligations. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight-line basis, as of the period ending date.

If we cannot reasonably estimate when our performance obligation either ceases or becomes inconsequential and perfunctory, then revenue is deferred until we can reasonably estimate when the performance obligation ceases or becomes inconsequential and perfunctory. Revenue is then recognized over the remaining estimated period of performance.

In addition, if we are involved in a steering committee as part of a multiple element arrangement that is accounted for as a single unit of accounting, we assess whether our involvement constitutes a performance obligation or a right to participate. Steering committee services that are not inconsequential or perfunctory and that are determined to be performance obligations are combined with other research services or performance obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which we expect to complete our aggregate performance obligations.

*Substantive Milestone Payments.* Our collaboration agreements may also contain substantive milestone payments. Collaboration agreements that contain substantive milestone payments are recognized upon achievement of the milestone only if the milestone meets all of the following criteria:

- be commensurate with either of the following:
  - a) the vendor's performance to achieve the milestone (for example, the achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement); or
  - b) the enhancement of the value of the deliverable as a result of a specific outcome resulting from the vendor's performance to achieve the milestone (or substantive effort on our part is involved in achieving the milestone);
- relates solely to past performance; and
- the amount of the milestone payment is reasonable relative to all deliverables and payment terms in the arrangement.

Determination as to whether a payment meets the aforementioned conditions involves management's judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone, and the resulting payment would be considered part of the consideration for the single unit of accounting and be recognized as revenue as such performance obligations are performed under either the relative performance or straight-line methods, as applicable, and in accordance with these policies as described above. In addition, the determination that one such payment was not a substantive milestone could prevent us from concluding that subsequent milestone payments were substantive milestones and, as a result, any additional milestone payments could also be considered part of the consideration for the single unit of accounting and

would be recognized as revenue as such performance obligations are performed under either the relative performance or straight-line methods, as applicable. Milestones that are tied to regulatory approval are not considered probable of being achieved until such approval is received. Milestones tied to counter-party performance are not included in our revenue model until the performance conditions are met.

*Reimbursement of Costs.* Reimbursement of research and development costs by third party collaborators has been historically recognized as revenue provided the provisions of FASB Codification Topic 605-45, *Revenue Recognition, Principal Agent Consideration*, are met, the amounts are determinable, and collection of the related receivable is reasonably assured.

*Royalty Revenue.* We expect to recognize royalty revenue upon the sale of the related products, provided that the royalty amounts are fixed or determinable, collection of the related receivable is reasonably assured and we have no remaining performance obligations under the arrangement. If royalties are received when we have remaining performance obligations, we expect to attribute the royalty payments to the services being provided under the arrangement and therefore recognize such royalty payments as such performance obligations are performed under either the relative performance or straight line methods, as applicable, and in accordance with these policies as described above. We have not recognized any royalty revenue to date but we expect that we will recognize royalties attributed to the sale of Erivedge in 2012.

*Deferred Revenue.* Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Significant judgments are required in the application of revenue recognition guidance. For example, in connection with our existing and former collaboration agreements, we have historically recorded on our balance sheet short- and long-term deferred revenue based on our best estimate of when such revenue would be recognized. Short-term deferred revenue would consist of amounts that are expected to be recognized as revenue, or applied against future co-development costs, within the next fiscal year. Amounts that we expect will not be recognized in the next fiscal year would be classified as long-term deferred revenue. However, this estimate would be based on our operating plan as of the balance sheet date and on our estimated performance periods under the collaboration in which we have recorded deferred revenues. If our operating plan or our estimated performance period would change, we could recognize a different amount of deferred revenue over the reporting period.

With respect to each of the foregoing areas of revenue recognition, we exercise significant judgment in determining whether an arrangement contains multiple elements, and, if so, how much revenue is allocable to each element. In addition, we exercise our judgment in determining when our significant obligations have been met under such agreements and the specific time periods over which we recognized revenue, such as non-refundable, up-front license fees. To the extent that actual facts and circumstances differ from our initial judgments, our revenue recognition with respect to such transactions would change accordingly and any such change could affect our reported operating results. To the extent that actual facts and circumstances differ from our initial judgments, our revenue recognition with respect to such arrangement would change accordingly and any such change could affect our reported financial results.

### ***Stock-based Compensation***

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards, or SFAS, No. 123 (revised 2004), *Share-Based Payment*, which generally requires that such transactions be accounted for using a fair-value-based method and is now referred to as FASB Codification Topic 718, *Compensation – Stock Compensation*.

We have recorded employee and director stock-based compensation expense of \$1,642,000, \$1,979,000 and \$1,750,000 for the years ended December 31, 2011, 2010 and 2009, respectively. We estimate that we will record approximately \$3,300,000, in stock-based compensation expense in 2012. We have granted and expect that we may grant additional options in 2012 that could increase the amount of stock-based compensation ultimately

recognized. The amount of the incremental employee stock-based compensation expense attributable to 2012 employee stock options to be granted will depend primarily on the number of stock options granted, the fair market value of our common stock at the respective grant dates, and the specific terms of the stock options.

We measure compensation cost for share-based compensation at fair value, including estimated forfeitures, and recognize the expense as compensation expense over the period that the recipient is required to provide service in exchange for the award, which generally is the vesting period. We use the Black-Scholes option pricing model to measure the fair value of stock options. This model requires significant estimates related to the award's expected life and future stock price volatility of the underlying equity security. In determining the amount of expense to be recorded, we also are required to estimate forfeiture rates for awards, based on the probability that employees will complete the required service period. We estimate the forfeiture rate based on historical experience. If actual forfeitures differ significantly from our estimates, additional adjustments to compensation expense may be required in future periods. Ultimately, the actual expense recognized over the vesting period will only be for those shares that vest.

### ***Fair Value Measurements***

Effective January 1, 2008, we adopted the provisions of SFAS No. 157, *Fair Value Measurements* for our financial assets and financial liabilities, which is now referred to as FASB Codification Topic 820, *Fair Value Measurements and Disclosures*. Topic 820 provides a framework for measuring fair value under GAAP and requires expanded disclosures regarding fair value measurements. GAAP defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers and sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact.

GAAP requires the use of valuation techniques that are consistent with the market approach, the income approach and/or the cost approach. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets and liabilities. The income approach uses valuation techniques to convert future amounts, such as cash flows or earnings, to a single present amount on a discounted basis. The cost approach is based on the amount that currently would be required to replace the service capacity of an asset (replacement cost). Valuation techniques should be consistently applied. GAAP also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

- Level 1** Quoted prices in active markets for identical assets or liabilities.
- Level 2** Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3** Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Our cash equivalents and marketable securities have been classified as either Level 1 or Level 2 assets. We do not hold any asset-backed or auction rate securities. Short-term accounts receivable and accounts payable are reflected in the consolidated financial statements at net realizable value, which approximates fair value due to the short-term nature of these instruments.

In 2010, we completed a registered direct offering in which we issued warrants to purchase shares of our common stock. The warrants include certain protective features for the benefit of the warrantholder, including an exercise price adjustment clause and a possible cash-settlement option in the event of a change of control until the later to occur of (i) two years from the date of original issuance of the warrant, or January 27, 2012 and

(ii) the date upon which Genentech or Roche submits a new drug application (NDA) for GDC-0449 (Erivedge) which occurred in September 2010. Due to these terms, the warrants were deemed to be a liability. We estimate the fair value of the warrants using a Black-Scholes option pricing model under various probability-weighted outcomes which take into consideration the protective, but limited, cash-settlement feature of the warrants. In using this model, the fair value is determined by applying Level 3 inputs, which have included assumptions around the estimated future stock price of our common stock and varying probabilities that certain events will occur. Significant increases or decreases in any of these assumptions would materially impact the fair value of the warrants and our financial statements. The warrants will be revalued each reporting period with updated assumptions, and the resulting change in fair value of the warrant liability will be recognized in our financial statements.

While we believe our valuation methodologies are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

### ***Long-lived Assets***

Long-lived assets consist primarily of property and equipment and goodwill. Property and equipment is stated at cost and depreciated over the estimated useful lives of the related assets using the straight-line method. Determining the economic lives of property and equipment requires us to make significant judgments that can materially impact our operating results. If it were determined that the carrying value of our other long-lived assets might not be recoverable based upon the existence of one or more indicators of impairment, we would measure an impairment based on application of FASB Codification Topic 360-10-05, *Impairment or Disposal of Long-Lived Assets*.

We evaluate our goodwill for impairment at least annually or more frequently if an indicator of potential impairment exists. In performing our evaluations of impairment, we determine fair value using widely accepted valuation techniques, including discounted cash flows. These calculations contain uncertainties as they require us to make assumptions related to future cash flows, projected useful lives of assets and the appropriate discount rate to reflect the risk inherent in future cash flows. We must also make assumptions regarding industry economic factors and the profitability of future business strategies. If actual results are not consistent with our estimates and assumptions used in estimating future cash flows and asset fair values, we may be exposed to a material impairment charge. As a single reporting unit, we completed our annual goodwill impairment tests in December 2011, 2010 and 2009, and determined that as of those dates our fair value exceeded the carrying value of our net assets. Accordingly, no goodwill impairment was recognized in 2011, 2010 and 2009.

Our discussion of our critical accounting policies is not intended to be a comprehensive discussion of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by generally accepted accounting principles, with no need for management's judgment in their application. There are also areas in which management's judgment in selecting any available alternative would not produce a materially different result.

**Results of Operations (all amounts rounded to the nearest thousand)**

***Years Ended December 31, 2011 and 2010***

*Revenues*

Total revenues are summarized as follows:

	For the Year Ended December 31,		Percentage Increase/ (Decrease)
	2011	2010	
Revenues:			
<b><i>Research and development</i></b>			
Genentech .....	\$ 388,000	\$ 275,000	41%
Other .....	75,000	69,000	9%
Subtotal .....	463,000	344,000	35%
<b><i>License fees</i></b>			
Genentech .....	14,000,000	—	100%
Debiopharm .....	—	11,333,000	(100%)
Micromet .....	—	4,000,000	(100%)
Other .....	300,000	323,000	(7%)
Subtotal .....	14,300,000	15,656,000	(9%)
Total Revenues .....	<u>\$14,763,000</u>	<u>\$16,000,000</u>	(8%)

Total revenues decreased by \$1,237,000, or 8%, for the year ended December 31, 2011 as compared to the prior year, primarily related to a decrease in our license fee revenues of \$1,356,000. During the year ended December 31, 2011, we recognized \$14,000,000 in license revenue for the achievement of FDA and EMA acceptances of Genentech's NDA and MAA filings, respectively, related to Erivedge which is under collaboration with Genentech. During the year ended December 31, 2010, we recorded license fee revenues of \$15,656,000, primarily comprised of an \$11,000,000 contingent payment from Debiopharm upon the achievement of development milestones under our license agreement with Debiopharm as well as settlement proceeds of \$4,000,000 that we received from Micromet pursuant to a settlement, mutual release and termination agreement that we entered into with Micromet in February 2010.

All potential future contingent payments under our Genentech and Debiopharm agreements are tied to clinical and regulatory objective milestones. Erivedge received FDA approval in January 2012 for which we earned a \$10,000,000 contingent payment and will receive royalties on any sales. If Erivedge receives EMA marketing authorization, we will be entitled to receive an additional milestone payment as well as royalties on any future net sales. Because the settlement with Micromet discharged and terminated all future payment obligations that would have arisen under the June 2001 agreement, we do not expect to receive any additional revenues from Micromet.

Research and development revenues increased by \$119,000, or 35%, for the year ended December 31, 2011 as compared to the prior year. Research and development revenues are limited to expenses that we incur under our collaborations, primarily Genentech, for which our collaborators are obligated to reimburse us.

## Operating Expenses

Research and development expenses are summarized as follows:

Research and Development Program	For the Year Ended December 31,		Percentage Increase/ (Decrease)
	2011	2010	
Hedgehog pathway inhibitor .....	\$ 192,000	\$ 192,000	—%
CUDC-101 .....	4,289,000	3,327,000	29%
CUDC-907 .....	3,201,000	—	100%
Debio 0932 .....	45,000	43,000	5%
Other network-targeted cancer programs .....	4,604,000	7,237,000	(36%)
Sublicense fees .....	715,000	9,000	7,844%
Net (gain)/loss on disposition of assets .....	(77,000)	(98,000)	(21%)
Stock-based compensation .....	724,000	663,000	9%
Total research and development expenses .....	<u>\$13,693,000</u>	<u>\$11,373,000</u>	20%

Our research and development expenses increased by \$2,320,000, or 20%, for the year ended December 31, 2011, as compared to the prior year. The increase in research and development expenses is the result of a \$962,000 increase in spending related to our CUDC-101 program, which primarily relates to outside services and clinical costs associated with several of our programs for CUDC-101, including our phase I expansion trial for which we completed patient dosing in October 2011, costs related to our phase I trial in locally advanced HPV-head and neck cancers and manufacturing and toxicology costs related to an oral formulation of CUDC-101. In addition, spending related to our CUDC-907 program increased \$3,201,000 over the prior year period as a result of shifting resources from our other network-targeted cancer programs. Our 2011 spending on our other network-targeted cancer programs decreased by \$2,633,000 when compared to 2010. CUDC-907 was selected as a development candidate in January 2011. During the year ended December 31, 2011, we also incurred expenses of \$700,000 in sublicense payments that we made as a result of receiving \$14,000,000 from Genentech during 2011 for the achievement of regulatory objectives related to Erivedge under our Hedgehog pathway inhibitor program. No such expenses were incurred under the Genentech collaboration during the year ended December 31, 2010.

We expect that a majority of our research and development expenses for the foreseeable future will be incurred in support of our efforts to advance CUDC-101, CUDC-907 and our other targeted cancer programs. In addition, we will be obligated to pay additional sublicense fees for milestone payments received upon achievement of certain regulatory objectives and royalty payments on net sales of Erivedge in the U.S. that we receive from Genentech.

General and administrative expenses are summarized as follows:

	For the Year Ended December 31,		Percentage Increase/ (Decrease)
	2011	2010	
Personnel .....	\$2,472,000	\$ 2,648,000	(7%)
Occupancy and depreciation .....	480,000	401,000	20%
Legal services .....	2,137,000	3,552,000	(40%)
Consulting and professional services .....	1,110,000	1,348,000	(18%)
Insurance costs .....	248,000	256,000	(3%)
Other general and administrative expenses .....	777,000	756,000	3%
Stock-based compensation .....	1,048,000	1,304,000	(20%)
Total general and administrative expenses .....	<u>\$8,272,000</u>	<u>\$10,265,000</u>	(19%)

General and administrative expenses decreased by \$1,993,000, or 19%, for the year ended December 31, 2011, as compared to the prior year. This decrease was related to a reduction in spending in several areas, primarily for legal services. During the year ended December 31, 2010, we incurred approximately \$1,526,000 in expenses related to an arbitration proceeding that we filed against our former collaborator that we did not incur in the current period. In addition, legal costs associated with various matters decreased \$212,000 from the prior year period. Offsetting these decreases in legal spending, our patent-related costs increased \$323,000 in the year ended December 31, 2011 as compared to the prior year period primarily related to fees for foreign patent, opposition and interference filings. Consulting and professional services decreased \$238,000 for the year ended December 31, 2011, as compared to the prior year. During the year ended December 31, 2010, we incurred consulting and professional services specifically related to business development efforts used to facilitate the licensing agreement with Debiopharm due upon receipt of the milestone payments we received in 2010 that were not incurred in 2011.

Personnel costs decreased \$176,000 primarily resulting from discretionary bonuses to our executive officers, the majority of which was paid upon receipt of contingent payments received from Debiopharm in 2010. Stock-based compensation also decreased \$256,000 from the prior year primarily related to vesting of certain performance-based stock options in the first quarter of 2010 that did not occur during 2011. Offsetting these decreases, our allocated occupancy costs increased \$79,000 for the year ended December 31, 2011.

*Change in fair value of warrant liability.* In connection with our January 2010 registered direct offering, we issued warrants to purchase an aggregate of 1,612,322 shares of common stock which became exercisable as of the closing of the transaction. The warrants have an initial exercise price of \$3.55 per share and have a five year term, and the fair value of the warrants was recorded as a long-term liability. The fair value of the warrants was estimated at \$2,181,000 on the January 2010 issuance date, and \$1,605,000 as of December 31, 2010, using a Black-Scholes option pricing model under various probability-weighted outcomes which take into consideration the protective, but limited, cash-settlement feature for the benefit of the warrant holder that includes a possible cash-settlement option in the event of a change of control until the later to occur of (i) two years from the date of original issuance of the warrant, or January 27, 2012, and (ii) the date upon which Genentech or Roche submits an NDA for Erivedge (vismodegib) which occurred in September 2011. The warrants will be revalued each reporting period, with the resulting gains and losses recorded as the change in fair value of warrant liability in the income statement. We estimated that the fair value of the warrants at December 31, 2010 was \$1,605,000 using this same model with the following assumptions assigned to the varying outcomes: expected volatilities of 77.1% and 91.5%, risk free interest rates ranging from 1.0% to 1.6%, expected lives of three to four years and no dividends. Expected volatility in both models was based on our historical volatility commensurate with the term of the warrants. We estimated that the fair value of the warrants at December 31, 2011 was \$4,361,000 using this same model with the following assumptions assigned to the varying outcomes: expected volatility of 78%, a risk free interest rate of 0.4%, expected life of three years and no dividends. We recorded a charge of \$2,756,000 and a gain of \$576,000 for the years ended December 31, 2011 and 2010, respectively, as a result of the increase in the fair value of the warrant liability from December 31, 2010 and issuance, primarily related to the increase in our stock price during this period.

#### *Other Income*

For the year ended December 31, 2011, interest and other income was \$100,000 as compared to \$627,000 for the year ended December 31, 2010, a decrease of \$527,000, or 84%. The decrease relates to federal tax grants totaling \$489,000 that we received in the fourth quarter of 2010 under the Patient Protection and Affordable Care Act of 2010 that we did not receive in 2011. In addition, interest income decreased \$38,000 from the prior year period due to lower investment balances throughout 2011 as compared to 2010.

#### *Net Loss Applicable to Common Stockholders*

As a result of the foregoing, we incurred a net loss applicable to common stockholders of \$9,859,000 for the year ended December 31, 2011, as compared to \$4,435,000 for the year ended December 31, 2010.



**Years Ended December 31, 2010 and 2009**

**Revenues**

Total revenues are summarized as follows:

	For the Year Ended December 31,		Percentage Increase/ (Decrease)
	2010	2009	
Revenues:			
<b>Research and development</b>			
Genentech .....	\$ 275,000	\$ 229,000	20%
Debiopharm .....	—	532,000	(100%)
Other .....	69,000	20,000	245%
Subtotal .....	344,000	781,000	(56%)
<b>License fees</b>			
Genentech .....	—	6,000,000	(100%)
Debiopharm .....	11,333,000	1,667,000	580%
Micromet .....	4,000,000	—	100%
Other .....	323,000	142,000	127%
Subtotal .....	15,656,000	7,809,000	100%
Total Revenues .....	<u>\$16,000,000</u>	<u>\$8,590,000</u>	86%

Total revenues increased by \$7,410,000, or 86%, to \$16,000,000 for the year ended December 31, 2010 as compared to \$8,590,000 for the prior year, primarily related to an increase in our license fee revenues. We recorded license fee revenue of \$333,000 and \$1,667,000 for the year ended December 31, 2010 and 2009, respectively, related to the amortization of the \$2,000,000 up-front license fee that we received in August 2009 under our license agreement with Debiopharm. The performance period under this license agreement began in August 2009 and concluded during the first quarter of 2010. During the year ended December 31, 2010, we also recorded license fee revenues of \$11,000,000, comprised of an \$8,000,000 contingent payment we received from Debiopharm upon acceptance by French regulatory authorities of Debiopharm's clinical trial application for Debio 0932 in February 2010 and a \$3,000,000 contingent payment we received from Debiopharm upon treatment of the fifth patient in this phase I clinical trial in July 2010.

During the year ended December 31, 2010, we also received settlement proceeds of \$4,000,000 from Micromet, a former collaborator, pursuant to the settlement, mutual release and termination agreement that we entered into with Micromet in February 2010. The settlement payment was made by Micromet to resolve a contract claim we filed related to our June 2001 agreement with Micromet, in which Micromet acquired certain intellectual property assets relating to our single chain antibodies, including patents and license agreements.

During the year ended December 31, 2009, we recognized \$6,000,000 in license revenue as a result of Genentech's initiation of a pivotal phase II clinical trial in advanced BCC.

## Operating Expenses

Research and development expenses are summarized as follows:

Research and Development Program	For the Year Ended December 31,		Percentage Increase/ (Decrease)
	2010	2009	
Hedgehog pathway inhibitor .....	\$ 192,000	\$ 495,000	(61%)
CUDC-101 (HDAC, EGFR, Her2 inhibitor) .....	3,327,000	1,568,000	112%
Debio 0932 (formerly CUDC-305) (Hsp90 inhibitor) .....	43,000	2,083,000	(98%)
Other network-targeted cancer programs .....	7,237,000	5,084,000	42%
Hedgehog small molecule agonist or protein .....	9,000	14,000	(36%)
Net (gain)/loss on disposition of assets .....	(98,000)	1,000	(9,900%)
Stock-based compensation .....	663,000	688,000	(4%)
Total research and development expenses .....	<u>\$11,373,000</u>	<u>\$9,933,000</u>	14%

Our research and development expenses increased by \$1,440,000, or 14%, for the year ended December 31, 2010, as compared to the prior year. The increase in research and development expenses was primarily the result of an increase of \$2,153,000 in spending relating to our preclinical network-targeted cancer programs from the prior year period as we continued to conduct research in our ongoing efforts to select additional preclinical candidates for future development. In addition, spending primarily related to outside services and clinical costs increased \$1,731,000 over the prior year period for our CUDC-101 program, for which we completed a phase I trial in April 2010 and initiated a phase Ib expansion trial in August 2010.

Offsetting these increases, spending related to the Debio 0932 program decreased \$2,040,000 from the prior year as Debiopharm assumed all future costs of the program following our entry into a license agreement with Debiopharm in August 2009. During the year ended December 31, 2009, we also incurred expenses of \$300,000 in sublicense payments that we made as a result of receiving \$6,000,000 from Genentech during 2009 for the achievement of a clinical development objective related to our Hedgehog pathway inhibitor program. No such expenses were incurred under the Genentech collaboration during the year ended December 31, 2010.

General and administrative expenses are summarized as follows:

	For the Year Ended December 31,		Percentage Increase/ (Decrease)
	2010	2009	
Personnel .....	\$ 2,648,000	\$2,123,000	25%
Occupancy and depreciation .....	401,000	344,000	17%
Legal services .....	3,552,000	2,543,000	40%
Consulting and professional services .....	1,348,000	1,548,000	(13%)
Insurance costs .....	256,000	282,000	(9%)
Other general and administrative expenses .....	756,000	696,000	9%
Stock-based compensation .....	1,304,000	1,166,000	12%
Total general and administrative expenses .....	<u>\$10,265,000</u>	<u>\$8,702,000</u>	18%

General and administrative expenses increased by \$1,563,000, or 18%, for the year ended December 31, 2010, as compared to the prior year. This increase was primarily due to increased spending of \$1,009,000 for legal services. We incurred \$1,526,000 for the year ended December 31, 2010 as compared to \$731,000 for the prior year in expenses related to the Micromet arbitration proceeding, an increase of \$795,000. The remainder of the increase in legal fees of \$214,000 resulted from costs associated with increased patent costs, including fees related to foreign patent filings. In addition, personnel costs increased \$525,000 primarily resulting from discretionary bonuses to our executive officers, the majority of which was paid upon receipt of contingent

payments received from Debiopharm in 2010. No bonuses were paid to our executive officers in 2009. In addition, our executive officers' compensation increased in the first quarter of 2010 to eliminate the pay reductions implemented in October 2008. Stock-based compensation also increased \$138,000 over the prior year primarily related to vesting of certain performance-based options in the first quarter of 2010. Finally, occupancy costs increased \$57,000 for the year ended December 31, 2010 as a result of rent expense for two locations during December 2010 as we completed the move to our new facility.

Offsetting these increases, consulting and professional services decreased \$200,000 from the prior year period primarily as the result of business development expenditures to facilitate the licensing agreement with Debiopharm in 2009.

*Change in fair value of warrant liability.* The fair value of the warrants issued in connection with our January 2010 registered direct offering was estimated at \$2,181,000 on the January 2010 issuance date, and \$1,605,000 as of December 31, 2010, using a Black-Scholes option pricing model. We estimated that the fair value of the warrants at issuance using this model with the following assumptions assigned to the varying outcomes: expected volatilities of 69.8% and 80%, risk free interest rates ranging from 1.42% to 2.38%, expected lives of three to five years and no dividends. We estimated that the fair value of the warrants at December 31, 2010 was \$1,605,000 using this same model with the following assumptions assigned to the varying outcomes: expected volatilities of 77.1% and 91.5%, risk free interest rates ranging from 1.0% to 1.6%, expected lives of three to four years and no dividends. Expected volatility in both models was based on our historical volatility commensurate with the term of the warrants. The fair value of the warrants was recorded as a long-term liability. We recorded a gain of approximately \$576,000 for the year ended December 31, 2010 as a result of the decrease in the fair value of the warrant liability from issuance in January 2010.

#### *Other Income*

For the year ended December 31, 2010, interest and other income was \$627,000 as compared to \$222,000 for the year ended December 31, 2009, an increase of \$405,000, or 182%. The increase relates to federal tax grants totaling \$489,000 that we received in the fourth quarter of 2010 under the Patient Protection and Affordable Care Act of 2010. We do not have any ongoing obligations under these awards and we do not expect to receive any future payments related to these grants. Offsetting this increase, interest income decreased \$84,000 from the prior year period due to lower interest rates for the year ended December 31, 2010 as compared to the year ended December 31, 2009.

#### *Net Loss Applicable to Common Stockholders*

As a result of the foregoing, we incurred a net loss applicable to common stockholders of \$4,435,000 for the year ended December 31, 2010, as compared to \$9,823,000 for the year ended December 31, 2009.

### **Liquidity and Capital Resources**

#### *Sources of Liquidity*

We have financed our operations primarily through license fees, contingent cash payments and research and development funding from our collaborators and licensors, the private and public placement of our equity securities, debt financings and the monetization of certain royalty rights. During the fourth quarter of 2011, we received \$14,000,000 in milestone payments from Genentech for the achievement of clinical development objectives for Erivedge. Erivedge received FDA approval in January 2012 for which we received an additional milestone payment of \$10,000,000 and we will be entitled to receive royalties on any future sales. If Erivedge receives EMA marketing authorization, we will be entitled to receive an additional milestone payment and royalties on any future sales.

On June 13, 2011, we entered into an At Market Issuance Sales Agreement, or ATM agreement, with McNicoll, Lewis & Vlak LLC, or MLV, pursuant to which we may issue and sell shares of our common stock, \$0.01 par value per share, with an aggregate offering price of up to \$20,000,000 from time to time through MLV. Upon delivery of a

placement notice and subject to the terms and conditions of the ATM agreement, MLV may sell the common stock by methods deemed to be an “at-the-market” offering as defined in Rule 415 of the Securities Act of 1933, including without limitation, sales made directly on The NASDAQ Global Market, on any other existing trading market for the common stock or to or through a market maker. With our prior written approval, MLV may also sell the common stock by any other method permitted by law, including in privately negotiated transactions. We or MLV may suspend or terminate the offering of common stock upon notice and subject to other conditions. MLV will act as sales agent on a commercially reasonable best efforts basis consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of NASDAQ. We will pay MLV a commission equal to 3.0% of the gross sales price per share sold, and we have agreed to provide indemnification and contribution to MLV against certain civil liabilities, including liabilities under the Securities Act. Since the inception of the ATM agreement, we have sold 104,118 shares of common stock under the ATM agreement raising approximately \$289,000 in gross proceeds, which was offset by offering expenses of approximately \$128,000.

At December 31, 2011, our principal sources of liquidity consisted of cash, cash equivalents, and marketable securities of \$37,718,000, excluding our restricted investment of \$236,000. Our cash and cash equivalents are highly liquid investments with a maturity of three months or less at date of purchase and consist of investments in money market funds with commercial banks and financial institutions, short-term commercial paper, and government obligations. We maintain cash balances with financial institutions in excess of insured limits.

#### *Cash Flows*

The use of our cash flows for operations has primarily consisted of salaries and wages for our employees, facility and facility-related costs for our office and laboratory, fees paid in connection with preclinical studies, laboratory supplies, consulting fees and legal fees. During 2008, we began incurring clinical costs associated with our phase I clinical trial of CUDC-101. We expect that costs associated with clinical studies will increase in future periods assuming that CUDC-101 advances into further stages of clinical testing and other of our network-targeted cancer drug candidates such as CUDC-907, reach clinical trials.

Net cash used in operating activities was \$4,563,000 for the year ended December 31, 2011, compared to \$1,629,000 for the year ended December 31, 2010. Cash used in operating activities during the year ended December 31, 2011 was primarily the result of our net loss for the period of \$9,859,000, offset by non-cash charges totaling \$4,805,000 consisting of stock-based compensation, changes in the fair value of our warrant liability, non-cash interest expense, depreciation and a gain on the sale of assets. In addition, changes in certain operating assets and liabilities affected operating cash during the year ended December 31, 2011, primarily related to an increase in our accounts payable and accrued liabilities of \$416,000.

Cash used in operating activities during the year ended December 31, 2010 was primarily the result of our net loss for the period of \$4,435,000. Our loss was partially offset by non-cash charges totaling \$1,663,000 consisting of stock-based compensation, changes in the fair value of our warrant liability, non-cash interest expense, depreciation and a gain on the sale of assets. In addition, changes in certain operating assets and liabilities affected operating cash during the year ended December 31, 2010, including an increase in our accounts payable and accrued liabilities of \$956,000 and a decrease of \$240,000 in prepaid expenses and other assets. The decrease of \$476,000 in deferred revenue primarily related to our August 2009 license agreement with Debiopharm and was offset by a decrease of \$423,000 in our accounts receivable.

We expect to continue to use cash in operations as we continue to seek to advance our targeted cancer drug programs through preclinical testing and into clinical development. In addition, in the future we may owe royalties and other contingent payments to our licensors based on the achievement of developmental milestones, product sales and other specified objectives.

Investing activities provided cash of \$9,776,000 for the year ended December 31, 2011 and used cash of \$14,889,000 for the year ended December 31, 2010, resulting primarily from net investment activity for the respective periods. During the year ended December 31, 2011, the restriction on our short-term investment ended

and we reduced our long-term restricted investment resulting in an increase in our available cash for the period of \$261,000. This increase in cash was offset by purchases of research equipment totaling \$260,000 during the year ended December 31, 2011. Our restricted investments increased by \$281,000 primarily related to a security deposit for a new facility lease entered into in September 2010 and we purchased \$275,000 in fixed assets during the year ended December 31, 2010.

Financing activities provided cash of \$2,081,000 for the year ended December 31, 2011, principally from the exercise of stock options and warrants and purchases of common stock under our employee stock purchase plan. We also received \$289,000 in net proceeds from sales of common stock under our ATM agreement with MLV. Financing activities provided cash of approximately \$17,069,000 for the year ended December 31, 2010, resulting principally from the issuance of 6,449,288 shares of common stock and warrants under our January 2010 registered direct offering, which provided \$14,942,000 in net proceeds. In addition, warrants for an aggregate of 1,742,671 shares of common stock were exercised under our August 2007 private placement providing approximately \$1,778,000 in proceeds. The remaining cash of \$350,000 was provided by the exercise of stock options and purchases of common stock under our employee stock purchase plan for the year ended December 31, 2010.

#### *Funding Requirements*

We have incurred significant losses since our inception. As of December 31, 2011, we had an accumulated deficit of approximately \$732,088,000. We will require substantial funds to continue our research and development programs and to fulfill our planned operating goals. In particular, our currently planned operating and capital requirements include the need for working capital to support our research and development activities for CUDC-101, CUDC-907 and other small molecules that we are seeking to develop from our pipeline of network-targeted cancer programs, and to fund our general and administrative costs and expenses.

Our ability to finance our company and to generate revenues will depend heavily on royalty payments from the commercial sale of Erivedge and the ability of Erivedge to be approved for commercial sale by the EMA, which would result in us becoming eligible to receive additional milestone payments as well as royalties on any future sales. Moreover, we have historically derived a substantial portion of our revenue from the research funding portion of our collaboration agreements. However, we have no current source of research funding revenue. We expect that our only source of cash flows from operations for the foreseeable future will be:

- up-front license payments and research and development funding that we may receive if we are able to successfully enter into new collaboration agreements;
- contingent cash payments that we may receive for the achievement of development objectives under any new collaborations or our existing collaborations with Genentech, Debiopharm and the LLS; and
- royalty payments that are contingent upon the successful commercialization of products based upon these collaborations.

We may not be able to successfully enter into or continue any corporate collaborations and the timing, amount and likelihood of us receiving payments under such collaborations is highly uncertain. As a result, we cannot assure you that we will attain any further revenue under any collaborations or licensing arrangements.

We anticipate that existing cash, cash equivalents, marketable securities and working capital at December 31, 2011, should enable us to maintain current and planned operations into the second half of 2013, including the \$10,000,000 milestone we earned in January 2012 upon FDA approval of Erivedge. Our future capital requirements, however, may vary from what we currently expect. There are a number of factors that may adversely affect our planned future capital requirements and accelerate our need for additional financing, many of which are outside our control, including the following:

- unanticipated costs in our research and development programs;
- the timing and cost of obtaining regulatory approvals for our drug candidates;
- the timing, receipt and amount of payments, if any, from current and potential future collaborators;

- the timing and amount of payments due to licensors of patent rights and technology used in our drug candidates;
- unplanned costs to prepare, file, prosecute, maintain and enforce patent claims and other patent-related costs, including litigation costs and technology license fees; and
- unexpected losses in our cash investments or an inability to otherwise liquidate our cash investments due to unfavorable conditions in the capital markets.

We may seek additional funding through public or private financings of debt or equity, including, but not limited to, sales under our ATM agreement with MLV. For example, in June 2011 we entered into an agreement with MLV pursuant to which, from time to time, we may offer and sell up to \$20 million of common stock through MLV pursuant to one or more “at the market” offerings. In addition, with our prior written approval, MLV may also sell these shares of common stock by any other method permitted by law, including in privately negotiated transactions. The market for emerging life science stocks in general, and the market for our common stock in particular, are highly volatile. Due to this and various other factors, including currently adverse general market conditions and the early-stage status of our development pipeline, additional funding may not be available to us on acceptable terms, if at all, and we may not be able to sell additional shares under the arrangement with MLV at favorable prices. In addition, the terms of any financing may be dilutive or otherwise adversely affect other rights of our stockholders. We also expect to seek additional funds through arrangements with collaborators, licensees or other third parties. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or drug candidates, and we may not be able to enter into such arrangements on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, whether through sales of debt or equity or through third party collaboration or license arrangements, we may be required to curtail or terminate some or all of our development programs, including some or all of our drug candidates.

### Contractual Obligations

As of December 31, 2011, we had future payments required under contractual obligations and other commitments, including an operating lease related to our facility, research services agreements, consulting agreements, and license agreements, as follows:

	Payment Due By Period (amounts in 000's)				
	Total	Less than One Year	One to Three Years	Three to Five Years	More than Five Years
Operating lease obligations(1) .....	\$3,892	\$ 578	\$1,229	\$1,327	\$758
Outside service obligations(2) .....	462	364	98	—	—
Licensing obligations(3) .....	119	119	—	—	—
Total future obligations .....	<u>\$4,473</u>	<u>\$1,061</u>	<u>\$1,327</u>	<u>\$1,327</u>	<u>\$758</u>

- (1) Effective September 16, 2010, we entered into a new lease agreement with the Trustees of Lexington Office Realty Trust pursuant to which we have agreed to lease 24,529 square feet of property to be used for office, research and laboratory space located at 4 Maguire Road in Lexington, Massachusetts, to which we relocated in December 2010. The term of the lease agreement commenced on December 1, 2010, and expires approximately seven years and two months from such date. The total remaining cash obligation for the base rent over the initial term of the lease agreement is approximately \$3,892,000. In addition to the base rent, we will also be responsible for our share of operating expenses and real estate taxes, in accordance with the terms of the lease agreement. Amounts include contractual rent payments and exclude any impact of an early termination payment as defined in the agreement.
- (2) Outside service obligations consist of agreements we have with outside labs, consultants and various other service organizations. Obligations to clinical research organizations, medical centers and hospitals

conducting our clinical trials are included in our financial statements for costs incurred as of December 31, 2011. Our obligations under these types of arrangements are limited to actual costs incurred for services performed and do not include any contingent or milestone payments.

- (3) Licensing obligations include only obligations that are known to us as of December 31, 2011. In the future, we may owe royalties and other contingent payments to our licensees based on the achievement of developmental milestones, product sales and specified other objectives. For example, upon receipt of the \$10,000,000 payment from Genentech as a result of FDA approval of Erivedge in January 2012, we will be obligated to make payments to our sublicensors totaling \$500,000, or 5%. We will also be obligated to pay a total of 5% of any royalties we receive upon the sale of Erivedge to these sublicensors. These future obligations are not reflected in the table above as these payments are contingent upon third-party regulatory approval(s) and/or commercial sales of Erivedge, which cannot be reasonably estimated at this time. Contingent payments to sublicensors related to future development milestones would total \$3,650,000, or 5%, if all of the \$73,000,000 in remaining milestones under our Genentech collaboration are achieved.

### **Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements as of December 31, 2011.

### **Inflation**

We believe that inflation has not had a significant impact on our revenue and results of operations since inception.

### **New Accounting Pronouncements**

In June 2011, the Financial Accounting Standards Board, or FASB, issued an amendment to the accounting guidance for presentation of comprehensive income. Under the amended guidance, a company may present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In either case, a company is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. Regardless of choice in presentation, the company is required to present on the face of the financial statements reclassification adjustments for items that are reclassified from other comprehensive income to net income in the statement(s) where the components of net income and the components of other comprehensive income are presented. For public companies, the amendment is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011, and shall be applied retrospectively with the exception of reclassification adjustments which are currently deferred while the FASB deliberates on this issue. Early adoption is permitted and we adopted this pronouncement in the fourth quarter of 2011. Other than a change in presentation, the adoption of this update did not have a material impact on our consolidated financial statements.

In September 2011, the FASB issued an Accounting Standards Update ("ASU") which simplifies how companies test goodwill for impairment. The amendments permit an entity to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test described in goodwill accounting standard. The amendments are effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. Early adoption is permitted. We do not expect the new ASU to have a material effect on our financial position, results of operations or cash flows.

## **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our current cash balances in excess of operating requirements are invested in cash equivalents and short-term marketable securities, which consist of time deposits and investments in money market funds with commercial banks and financial institutions, short-term commercial paper, and government obligations with an average maturity of less than one year. All marketable securities are considered available for sale. The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. This objective may be adversely affected by the ongoing economic downturn and volatile business environment and continued unpredictable and unstable market conditions. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. While as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or marketable securities since December 31, 2011, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or marketable securities or our ability to meet our financing objectives. Further dislocations in the credit market may adversely impact the value and/or liquidity of marketable securities owned by us. Our investments are investment grade securities, and deposits are with investment grade financial institutions. We believe that the realization of losses due to changes in credit spreads is unlikely as we currently have the ability to hold our investments for a sufficient period of time to recover the fair value of the investment and there is sufficient evidence to indicate that the fair value of the investment is recoverable. We do not use derivative financial instruments in our investment portfolio. We do not believe that a 10% change in interest rate percentages would have a material impact on the fair value of our investment portfolio or our interest income.



## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

### Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of management and our directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of evaluations of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2011. In making this assessment our management used the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO.

Based on our assessment, management concluded that, as of December 31, 2011, our internal control over financial reporting is effective based on the criteria established in *Internal Control—Integrated Framework* issued by COSO.

The effectiveness of internal control over financial reporting as of December 31, 2011 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Curis, Inc.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations and comprehensive loss, of stockholders' equity and of cash flows present fairly, in all material respects, the financial position of Curis, Inc. and its subsidiaries at December 31, 2011 and 2010, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2011 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PRICEWATERHOUSECOOPERS LLP

Boston, Massachusetts

February 29, 2012

# CURIS, INC. AND SUBSIDIARIES

## Consolidated Balance Sheets

	December 31,	
	2011	2010
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents .....	\$ 15,119,730	\$ 7,826,549
Marketable securities .....	22,597,845	32,553,269
Short-term investment – restricted .....	—	219,458
Accounts receivable .....	42,067	92,371
Prepaid expenses and other current assets .....	743,799	392,249
Total current assets .....	38,503,441	41,083,896
Property and equipment, net .....	455,730	302,721
Long-term investment – restricted .....	235,914	277,546
Goodwill .....	8,982,000	8,982,000
Other assets .....	2,980	2,980
Total assets .....	\$ 48,180,065	\$ 50,649,143
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable .....	\$ 2,364,437	\$ 2,620,968
Accrued liabilities .....	1,422,107	854,605
Total current liabilities .....	3,786,544	3,475,573
Warrants .....	4,361,168	1,604,742
Other long-term liabilities .....	156,396	51,171
Total liabilities .....	8,304,108	5,131,486
Commitments		
Stockholders' Equity:		
Common stock, \$0.01 par value—125,000,000 shares authorized; 78,165,360 shares issued and 77,117,653 shares outstanding at December 31, 2011; and 76,803,868 shares issued and 75,756,161 shares outstanding at December 31, 2010 .....	781,654	768,039
Additional paid-in capital .....	772,039,254	767,825,232
Treasury stock (at cost, 1,047,707 shares) .....	(891,274)	(891,274)
Deferred compensation .....	—	(955)
Accumulated deficit .....	(732,087,642)	(722,228,747)
Accumulated other comprehensive income .....	33,965	45,362
Total stockholders' equity .....	39,875,957	45,517,657
Total liabilities and stockholders' equity .....	\$ 48,180,065	\$ 50,649,143

The accompanying notes are an integral part of these consolidated financial statements.

**CURIS, INC. AND SUBSIDIARIES**  
**Consolidated Statements of Operations and Comprehensive Loss**

	<b>Years Ended December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
Revenues:			
Research and development .....	\$ 462,580	\$ 343,732	\$ 780,773
License fees .....	14,300,000	15,655,833	7,809,167
Total revenues .....	<u>14,762,580</u>	<u>15,999,565</u>	<u>8,589,940</u>
Costs and Expenses:			
Research and development .....	13,692,659	11,372,850	9,932,768
General and administrative .....	8,272,424	10,264,459	8,702,082
Total costs and expenses .....	<u>21,965,083</u>	<u>21,637,309</u>	<u>18,634,850</u>
Loss from operations .....	<u>(7,202,503)</u>	<u>(5,637,744)</u>	<u>(10,044,910)</u>
Other (Expense) Income:			
Interest income .....	100,034	137,662	222,309
Change in fair value of warrant liability .....	(2,756,426)	575,813	—
Other income .....	—	488,959	—
Total other (expense) income .....	<u>(2,656,392)</u>	<u>1,202,434</u>	<u>222,309</u>
Net loss .....	<u>\$ (9,858,895)</u>	<u>\$ (4,435,310)</u>	<u>\$ (9,822,601)</u>
Net Loss per Common Share (Basic and Diluted) .....	<u>\$ (0.13)</u>	<u>\$ (0.06)</u>	<u>\$ (0.15)</u>
Weighted Average Common Shares (Basic and Diluted) .....	<u>76,351,856</u>	<u>74,959,158</u>	<u>65,060,514</u>
Net Loss .....	\$ (9,858,895)	\$ (4,435,310)	\$ (9,822,601)
Other comprehensive loss, net of tax:			
Unrealized gain (loss) on marketable securities .....	(11,397)	44,725	(90,869)
Comprehensive loss .....	<u>\$ (9,870,292)</u>	<u>\$ (4,390,585)</u>	<u>\$ (9,913,470)</u>

The accompanying notes are an integral part of these consolidated financial statements.

**CURIS, INC. AND SUBSIDIARIES**  
**Consolidated Statements of Stockholders' Equity**

	<u>Common Stock</u>		<u>Additional</u>	<u>Treasury</u>	<u>Deferred</u>	<u>Accumulated</u>	<u>Accumulated</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Paid-in</u>	<u>Stock</u>	<u>Compensation</u>	<u>Deficit</u>	<u>Other</u>	<u>Stockholders'</u>
			<u>Capital</u>				<u>Comprehensive</u>	<u>Equity</u>
							<u>Income</u>	
Balance, December 31, 2008 .....	64,701,405	\$647,014	\$745,360,736	\$(891,274)	\$ (12,550)	\$(707,970,836)	\$ 91,506	\$37,224,596
Issuances of common stock upon the exercise of warrants .....	3,028,188	30,282	3,058,470	—	—	—	—	3,088,752
Other issuances of common stock .....	630,474	6,305	791,840	—	—	—	—	798,145
Recognition of employee stock-based compensation .....	—	—	1,749,798	—	—	—	—	1,749,798
Mark-to-market on stock options to non-employees .....	—	—	107,791	—	(107,791)	—	—	—
Amortization of deferred compensation .....	—	—	—	—	104,437	—	—	104,437
Other comprehensive loss .....	—	—	—	—	—	—	(90,869)	(90,869)
Net loss .....	—	—	—	—	—	(9,822,601)	—	(9,822,601)
Balance, December 31, 2009 .....	68,360,067	683,601	751,068,635	(891,274)	(15,904)	(717,793,437)	637	33,052,258
Issuance of common stock in conjunction with the registered direct offering, net of issuance costs of \$1,310,000 and net of fair value of warrants of \$2,180,555 .....	6,449,288	64,493	12,697,269	—	—	—	—	12,761,762
Issuances of common stock upon the exercise of warrants .....	1,742,671	17,427	1,760,097	—	—	—	—	1,777,524
Other issuances of common stock .....	251,842	2,518	347,058	—	—	—	—	349,576
Recognition of employee stock-based compensation .....	—	—	1,979,090	—	—	—	—	1,979,090
Mark-to-market on stock options to non-employees .....	—	—	(26,917)	—	26,917	—	—	—
Amortization of deferred compensation .....	—	—	—	—	(11,968)	—	—	(11,968)
Other comprehensive income .....	—	—	—	—	—	—	44,725	44,725
Net loss .....	—	—	—	—	—	(4,435,310)	—	(4,435,310)
Balance, December 31, 2010 .....	76,803,868	768,039	767,825,232	(891,274)	(955)	(722,228,747)	45,362	45,517,657
Issuances of common stock upon the exercise of warrants and stock options, for purchases under the ESPP, and pursuant to sales of shares under the Company's ATM agreement (see Note 9), net of \$128,155 in ATM issuance costs .....	1,361,492	13,615	2,442,866	—	—	—	—	2,456,481
Recognition of employee stock-based compensation .....	—	—	1,641,830	—	—	—	—	1,641,830
Mark-to-market on stock options to non-employees .....	—	—	129,326	—	955	—	—	130,281
Other comprehensive loss .....	—	—	—	—	—	—	(11,397)	(11,397)
Net loss .....	—	—	—	—	—	(9,858,895)	—	(9,858,895)
Balance, December 31, 2011 .....	78,165,360	\$781,654	\$772,039,254	\$(891,274)	\$ —	\$(732,087,642)	\$ 33,965	\$39,875,957

The accompanying notes are an integral part of these consolidated financial statements.

**CURIS, INC. AND SUBSIDIARIES**  
**Consolidated Statements of Cash Flows**

	Years Ended December 31,		
	2011	2010	2009
<b>Cash Flows from Operating Activities:</b>			
Net loss .....	\$ (9,858,895)	\$ (4,435,310)	\$ (9,822,601)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization .....	107,396	686,495	751,213
Stock-based compensation expense .....	1,772,111	1,967,122	1,854,235
Change in fair value of warrant liability .....	2,756,426	(575,813)	—
Non-cash interest expense/(income) .....	246,122	(316,560)	—
Gain on sale of fixed assets and equipment .....	(77,068)	(98,107)	—
Impairment on property and equipment .....	—	—	1,071
Changes in operating assets and liabilities:			
Accounts receivable .....	50,304	423,387	(408,417)
Prepaid expenses and other assets .....	24,111	239,934	(253,810)
Accounts payable and accrued and other liabilities .....	416,196	955,586	(186,118)
Deferred revenue .....	—	(475,833)	475,833
Total adjustments .....	5,295,598	2,806,211	2,234,007
Net cash used in operating activities .....	(4,563,297)	(1,629,099)	(7,588,594)
<b>Cash Flows from Investing Activities:</b>			
Purchase of marketable securities .....	(42,136,949)	(65,897,078)	(35,825,838)
Sale of marketable securities .....	51,834,854	51,464,558	36,669,705
Decrease/(increase) in restricted cash/investments .....	261,090	(281,002)	(5,995)
Expenditures for property and equipment .....	(260,405)	(274,840)	(19,537)
Proceeds from sale of fixed assets and equipment .....	77,068	99,160	—
Net cash provided by (used in) investing activities .....	9,775,658	(14,889,202)	818,335
<b>Cash Flows from Financing Activities:</b>			
Proceeds from issuance of common stock associated with offerings, net of issuance costs (see Note 9) .....	288,817	14,942,317	—
Proceeds from issuance of common stock under the Company's share-based compensation plans and warrant exercises .....	1,792,003	2,127,100	3,886,897
Net cash provided by financing activities .....	2,080,820	17,069,417	3,886,897
Net increase (decrease) in cash and cash equivalents .....	7,293,181	551,116	(2,883,362)
Cash and cash equivalents, beginning of period .....	7,826,549	7,275,433	10,158,795
Cash and cash equivalents, end of period .....	<u>\$ 15,119,730</u>	<u>\$ 7,826,549</u>	<u>\$ 7,275,433</u>
Supplemental cash flow data related to non-cash items:			
Receivable for issuances of common stock .....	<u>\$ 375,661</u>	<u>\$ —</u>	<u>\$ —</u>

The accompanying notes are an integral part of these consolidated financial statements.

**CURIS, INC. AND SUBSIDIARIES**  
**Notes to Consolidated Financial Statements**

**(1) OPERATIONS**

Curis, Inc. (the “Company” or “Curis”) is a drug discovery and development company that is committed to leveraging its innovative signaling pathway drug technologies in seeking to develop next generation network-targeted cancer therapies. Curis is building upon its past experiences in targeting signaling pathways, including the Hedgehog signaling pathway, in its efforts to develop network-targeted cancer therapies. Curis conducts research programs both internally and through strategic collaborations.

The Company operates in a single reportable segment, which is the research and development of innovative cancer therapeutics. The Company expects that any successful products would be used in the health care industry and would be regulated in the United States by the U.S. Food and Drug Administration, or FDA, and in overseas markets by similar regulatory agencies.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to: development by its competitors of new or better technological innovations; dependence on key personnel; its ability to protect proprietary technology; its ability to successfully advance discovery, preclinical and clinical stage drug candidates in its internally funded programs; unproven technologies and drug development approaches; reliance on corporate collaborators and licensees to successfully research, develop and commercialize products based on the Company’s technologies; its ability to comply with FDA regulations and approval requirements; its ability to execute on its business strategies; and its ability to obtain adequate financing to fund its operations.

The Company’s future operating results will largely depend on the magnitude of payments from its current and potential future corporate collaborators and the progress of drug candidates currently in its research and development pipeline. The results of the Company’s operations will vary significantly from year to year and quarter to quarter and depend on, among other factors, the timing of its entry into new collaborations, if any, the timing of the receipt of payments from new or existing collaborators and the cost and outcome of any preclinical development or clinical trials then being conducted. The Company anticipates that existing capital resources at December 31, 2011 should enable the Company to maintain its current and planned operations into the second half of 2013, including the \$10,000,000 milestone earned in January 2012 upon FDA approval of Erivedge (see Note 13), and excluding any royalty payments the Company may receive upon the sale of Erivedge. The Company’s ability to continue funding its planned operations into and beyond the second half of 2013 is dependent upon, among other things, the success of its collaborations with Genentech and Debiopharm and receipt of additional cash payments under these collaborations, its ability to control expenses and its ability to raise additional funds through equity or debt financings, which includes the Company’s at-the-market sales agreement discussed in Note 9, new collaborations or other sources of financing. The Company may not be able to successfully enter into or continue any corporate collaborations and the timing, amount and likelihood of the Company receiving payments under such collaborations is highly uncertain. As a result, the Company cannot assure that it will attain any further revenue under any collaborations or licensing arrangements. If the Company is unable to obtain adequate financing, the Company may be required to reduce or delay spending on its research and/or development programs.

**(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**(a) USE OF ESTIMATES**

The preparation of the Company’s consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts and disclosure of revenue, expenses and certain assets and

liabilities at the balance sheet date. Such estimates include the performance obligations under the Company's collaboration agreements, the collectibility of receivables, the carrying value of property and equipment and intangible assets, the assumptions used in the Company's valuation of stock-based compensation and the value of certain investments and liabilities, including our long-term warrant liability. Actual results may differ from such estimates.

(b) CONSOLIDATION

The accompanying consolidated financial statements include the Company and its wholly owned subsidiaries, Curis Securities Corporation, Inc. and Curis Pharmaceuticals (Shanghai) Co., Ltd., or Curis Shanghai. The Company has eliminated all intercompany transactions in each of the years ended December 31, 2011, 2010 and 2009.

(c) REVENUE RECOGNITION

The Company's business strategy includes entering into collaborative license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of the Company's product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of clinical development and regulatory objectives, and royalties on product sales. The Company follows the provisions of Financial Accounting Standards Board, or FASB, Codification Topic 605, Revenue Recognition.

License Fees and Multiple Element Arrangements

In January 2010, the Company adopted a new U.S. generally accepted accounting principles, or GAAP, accounting standard on a prospective basis which amends existing revenue recognition accounting guidance to provide accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This new guidance eliminates the requirement to establish objective evidence of fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no vendor-specific objective evidence or third-party evidence to determine the fair value of that undelivered item. The Company did not enter into any multiple element arrangements or modify its existing collaborations during the years ended December 31, 2011 and 2010. The adoption of the new standard did not have an impact on the Company's financial statements.

For multiple element arrangements, including license agreements, entered into prior to January 1, 2010, guidance required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. Under this guidance, if the fair value of all of the undelivered elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined.

Non-refundable license fees are recognized as revenue when the Company has a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and the Company has no further performance obligations under the license agreement. Multiple element arrangements, such as license and development arrangements are analyzed to determine whether the deliverables, which often include a license and performance obligations such as research and steering committee services, can be separated or whether they must be accounted for as a single unit of accounting in accordance with U.S. GAAP. The Company recognizes up-front license payments as revenue upon delivery of the license only if the license has stand-alone



value and the fair value of the undelivered performance obligations, typically including research and/or steering committee services, can be determined. If the fair value of the undelivered performance obligations can be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have stand-alone value or (ii) have stand-alone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting and the license payments and payments for performance obligations are recognized as revenue over the estimated period of when the performance obligations are performed.

If the Company is involved in a steering committee as part of a multiple element arrangement that is accounted for as a single unit of accounting, the Company assesses whether its involvement constitutes a performance obligation or a right to participate. Steering committee services that are determined to be performance obligations are combined with other research services or performance obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which the Company expects to complete its aggregate performance obligations.

Whenever the Company determines that an arrangement should be accounted for as a single unit of accounting, it must determine the period over which the performance obligations will be performed and revenue will be recognized. Revenue will be recognized using either a relative performance or straight-line method. The Company recognizes revenue using the relative performance method provided that the Company can reasonably estimate the level of effort required to complete its performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Direct labor hours or full-time equivalents are typically used as the measure of performance. Revenue recognized under the relative performance method would be determined by multiplying the total payments under the contract, excluding royalties and payments contingent upon achievement of substantive milestones, by the ratio of level of effort incurred to date to estimated total level of effort required to complete the Company's performance obligations under the arrangement. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the relative performance method, as of each reporting period.

If the Company cannot reasonably estimate the level of effort required to complete its performance obligations under an arrangement, the performance obligations are provided on a best-efforts basis and the Company can reasonably estimate when the performance obligation ceases or the remaining obligations become inconsequential and perfunctory, then the total payments under the arrangement, excluding royalties and payments contingent upon achievement of substantive milestones, would be recognized as revenue on a straight-line basis over the period the Company expects to complete its performance obligations. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight-line basis, as of the period ending date.

If the Company cannot reasonably estimate when its performance obligation either ceases or becomes inconsequential and perfunctory, then revenue is deferred until the Company can reasonably estimate when the performance obligation ceases or becomes inconsequential. Revenue is then recognized over the remaining estimated period of performance.

Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations under an arrangement.

#### Substantive Milestone Payments

In April 2010, the FASB issued guidance on the milestone method for revenue recognition purposes. Previously, definitive guidance on when the use of the milestone method was appropriate did not exist. This guidance provides a framework of the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. This guidance was effective on a prospective

basis for milestones achieved in fiscal years and interim periods within those years, beginning on or after June 15, 2010 with early adoption permitted. The adoption of this guidance on January 1, 2011 did not materially change the Company's previous method of recognizing milestone payments and the adoption did not have a material impact on the Company's financial statements.

Collaboration agreements that contain substantive milestone payments are recognized upon achievement of the milestone only if the milestone meets all of the following criteria:

- be commensurate with either of the following:
  - c) the vendor's performance to achieve the milestone (for example, the achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement); or
  - d) the enhancement of the value of the deliverable as a result of a specific outcome resulting from the vendor's performance to achieve the milestone (or substantive Company effort is involved in achieving the milestone);
- relates solely to past performance;
- the amount of the milestone payment is reasonable relative to all deliverables and payment terms in the arrangement.

Determination as to whether a payment meets the aforementioned conditions involves management's judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone, and the resulting payment would be considered part of the consideration for the single unit of accounting and would be recognized as revenue as such performance obligations are performed under either the relative performance or straight-line methods, as applicable, and in accordance with these policies as described above. In addition, the determination that one such payment was not a substantive milestone could prevent the Company from concluding that subsequent milestone payments were substantive milestones and, as a result, any additional milestone payments could also be considered part of the consideration for the single unit of accounting and would be recognized as revenue as such performance obligations are performed under either the relative performance or straight-line methods, as applicable. Milestones that are tied to regulatory approval are not considered probable of being achieved until such approval is received. Milestones tied to counterparty performance are not included in the Company's revenue model until the performance conditions are met.

#### Reimbursement of Costs

Reimbursement of research and development costs by third party collaborators has been historically recognized as revenue provided the Company has determined that it is acting primarily as a principal in the transaction according to the provisions outlined in FASB Codification Topic 605-45, *Revenue Recognition, Principal Agent Considerations*, the amounts are determinable and collection of the related receivable is reasonably assured.

#### Royalty Revenue

Royalty revenue is recognized upon the sale of the related products, provided that the royalty amounts are fixed or determinable, collection of the related receivable is reasonably assured and the Company has no remaining performance obligations under the arrangement. If royalties are received when the Company has remaining performance obligations, the royalty payments would be attributed to the services being provided under the arrangement and therefore would be recognized as such performance obligations are performed under either the relative performance or straight line methods, as applicable, and in accordance with these policies as described above.

### Deferred Revenue

Amounts received prior to satisfying the above revenue recognition criteria would be recorded as deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized during the year ending December 31, 2012 would be classified as long-term deferred revenue. As of December 31, 2011, the Company had no amounts classified as short-term or long-term deferred revenue.

### Summary

During the years ended December 31, 2011, 2010 and 2009, total gross revenues from major current and former licensees as a percent of total gross revenues of the Company were as follows:

	<b>Year Ended December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
Genentech .....	97%	2%	73%
Debiopharm .....	—%	71%	26%
Micromet settlement proceeds .....	—%	25%	—%

#### (d) RESEARCH AND DEVELOPMENT

Research and development costs, including internal and external costs, are charged to operations as incurred. Research and development costs include personnel costs, lab supplies, outside services including clinical research organizations, medicinal chemistry, sublicense payments to licensors, consulting agreements, allocations of facility costs and fringe benefits, and other costs.

#### (e) CASH EQUIVALENTS, MARKETABLE SECURITIES AND INVESTMENTS

Cash equivalents consist of short-term, highly liquid investments purchased with original maturities of three months or less. All other liquid investments are classified as marketable securities. The Company's marketable securities are investments with original maturities of greater than three months from the date of purchase, but less than twelve months from the balance sheet date, and consist of commercial paper, corporate bonds and notes, and government obligations. These amounts are invested directly in commercial paper of financial institutions and corporations with A-/Aa3 or better long-term ratings and A-1/P-1 short term debt ratings and U.S. Treasury securities. All of the Company's marketable securities have been designated as available-for-sale and are stated at market value with any unrealized holding gains or losses included as a component of stockholders' equity and any realized gains and losses recorded in the statement of operations in the period the securities are sold.

The amortized cost, unrealized gains and fair value of marketable securities available-for-sale as of December 31, 2011, with maturity dates ranging between one and twelve months and with a weighted average maturity of 3.7 months are as follows:

	<b>Amortized Cost</b>	<b>Unrealized Gain</b>	<b>Fair Value</b>
U.S. Government obligations .....	\$ 3,808,641	\$ 63	\$ 3,808,704
Corporate bonds, notes and stock .....	18,787,778	1,363	18,789,141
Total marketable securities .....	<u>\$22,596,419</u>	<u>\$1,426</u>	<u>\$22,597,845</u>

The amortized cost, unrealized losses and fair value of marketable securities available-for-sale as of December 31, 2010, with maturity dates ranging between one and twelve months and with a weighted average maturity of 3.4 months are as follows:

	<b>Amortized Cost</b>	<b>Unrealized Loss</b>	<b>Fair Value</b>
U.S. Government obligations .....	\$ 3,601,240	\$ (716)	\$ 3,600,524
Corporate bonds and notes .....	28,955,486	(2,741)	28,952,745
Total marketable securities .....	<u>\$32,556,726</u>	<u>\$(3,457)</u>	<u>\$32,553,269</u>

(f) FAIR VALUE OF FINANCIAL INSTRUMENTS

The Company discloses fair value measurements based on a framework outlined by GAAP which requires expanded disclosures regarding fair value measurements. GAAP also defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers and sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact.

FASB Codification Topic 820, *Fair Value Measurements and Disclosures*, requires the use of valuation techniques that are consistent with the market approach, the income approach and/or the cost approach. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets and liabilities. The income approach uses valuation techniques to convert future amounts, such as cash flows or earnings, to a single present amount on a discounted basis. The cost approach is based on the amount that currently would be required to replace the service capacity of an asset (replacement cost). Valuation techniques should be consistently applied. GAAP also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

**Level 1** Quoted prices in active markets for identical assets or liabilities.

**Level 2** Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

**Level 3** Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. The Company's warrant liability was valued at issuance and at December 31, 2011 and 2010 using a probability-weighted Black-Scholes model, discussed further in Note 9, and is therefore classified as Level 3.

In accordance with the fair value hierarchy, the following table shows the fair value as of December 31, 2011 and 2010, of those financial assets that are measured at fair value on a recurring basis, according to the valuation techniques the Company used to determine their fair market value. No financial assets are measured at fair value on a nonrecurring basis at December 31, 2011 and 2010.

	Quoted Prices in Active Markets (Level 1)	Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)	Fair Value
<b>As of December 31, 2011:</b>				
Cash equivalents				
Money market funds .....	\$ 5,366,747	\$ —	\$—	\$ 5,366,747
Municipal bonds .....	2,375,000	—	—	2,375,000
Investments				
US government obligations .....	—	3,808,704	—	3,808,704
Corporate commercial paper, stock, bonds and notes .....	7,365,841	11,423,300	—	18,789,141
Total assets at fair value .....	<u>\$15,107,588</u>	<u>\$15,232,004</u>	<u>\$—</u>	<u>\$30,339,592</u>
<b>As of December 31, 2010:</b>				
Cash equivalents				
Money market funds .....	\$ 3,862,558	\$ —	\$—	\$ 3,862,558
Municipal bonds .....	2,330,000	—	—	2,330,000
Investments				
US government obligations .....	—	3,600,524	—	3,600,524
Corporate commercial paper, bonds and notes .....	10,333,931	18,618,814	—	28,952,745
Total assets at fair value .....	<u>\$16,526,489</u>	<u>\$22,219,338</u>	<u>\$—</u>	<u>\$38,745,827</u>

The Company classifies its commercial paper, government obligations and certain of its corporate notes and bonds as Level 2 under the fair value hierarchy. The Company has revised the 2010 table to classify \$3,600,524 of government obligations and \$18,618,814 of commercial paper and corporate notes as Level 2, which were previously classified as Level 1. Such revision had no impact on the Company's results of operations or financial condition as of December 31, 2010.

The above table excludes restricted investments that the Company held of \$235,914 and \$497,004 as of December 31, 2011 and 2010, respectively.

The following table rolls forward the fair value of the Company's warrant liability, the fair value of which is determined by Level 3 inputs for the years ended December 31, 2011 and 2010:

Balance at December 31, 2009 .....	\$ —
Issuance of warrants .....	2,180,555
Change in fair value .....	(575,813)
Balance at December 31, 2010 .....	<u>\$1,604,742</u>
Change in fair value .....	<u>2,756,426</u>
Balance at December 31, 2011 .....	<u><u>\$4,361,168</u></u>

(g) LONG-LIVED ASSETS OTHER THAN GOODWILL

Long-lived assets other than goodwill consist primarily of property and equipment and a restricted long-term investment. The aggregate balances for these long-lived assets were \$694,624 and \$583,247 as of December 31, 2011 and 2010, respectively. The Company applies the guidance in FASB Codification Topic 360-10-05, *Impairment or Disposal of Long-Lived Assets*. If it were determined that the carrying value of the Company's other long-lived assets might not be recoverable based upon the existence of one or more indicators of impairment, the Company would measure an impairment based on application of GAAP. The Company recognized impairment charges of \$1,000 in each of the years ended December 31, 2010 and 2009 related to certain equipment with no current or planned future use. The Company did not recognize any impairment charges for the year ended December 31, 2011.

Purchased equipment is recorded at cost. The Company does not currently hold any leased equipment. Depreciation and amortization are provided on the straight-line method over the estimated useful lives of the related assets or the remaining terms of the leases, whichever is shorter, as follows:

<u>Asset Classification</u>	<u>Estimated Useful Life</u>
Laboratory equipment, computers and software	3-5 years
Leasehold improvements	Lesser of life of the lease or the life of the asset
Office furniture and equipment	5 years

(h) GOODWILL

As of December 31, 2011 and 2010, the Company had recorded goodwill of \$8,982,000. The Company applies the guidance in FASB Codification Topic 350, *Intangibles – Goodwill and Other*. During each of December 2011, 2010 and 2009, the Company completed its annual goodwill impairment tests and determined that the Company represented a single reporting unit and as of those dates the fair value of the Company exceeded the carrying value of its net assets. Accordingly, no goodwill impairment was recognized for the years ended December 31, 2011, 2010 and 2009.

(i) **TREASURY STOCK**

On May 31, 2002, the Company announced that its Board of Directors had approved the repurchase of up to \$3,000,000 of the Company's common stock. The Company accounts for its common stock repurchases as treasury stock under the cost method. In 2002, the Company repurchased 1,047,707 shares of its common stock at a cost of \$891,000 pursuant to this repurchase program, and the Company has not purchased any shares since 2002.

(j) **BASIC AND DILUTED LOSS PER COMMON SHARE**

Basic and diluted net losses per share were determined by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is the same as basic net loss per common share for all periods presented, as the effect of the potential common stock equivalents is antidilutive due to the Company's net loss position for all periods presented. Antidilutive securities consist of stock options and warrants outstanding as of the respective reporting period. Antidilutive securities as of December 31, 2011, 2010 and 2009 consisted of the following:

	For the years ended December 31,		
	2011	2010	2009
Stock options outstanding .....	11,094,241	11,537,750	11,141,831
Warrants outstanding .....	1,610,818	1,612,322	1,742,671
Total antidilutive securities .....	<u>12,705,059</u>	<u>13,150,072</u>	<u>12,884,502</u>

(k) **STOCK-BASED COMPENSATION**

The Company adopted Statement of Financial Accounting Standards, or SFAS, No. 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)), which established standards for the accounting of transactions in which an entity exchanges its equity instruments for goods or services, and is now referred to as FASB Codification Topic 718, *Compensation – Stock Compensation*. Topic 718 focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. Topic 718 requires that the fair value of such equity instruments be recognized as an expense in the financial statements as services are performed.

(l) **OPERATING LEASES**

The Company currently has one facility located at 4 Maguire Road in Lexington, Massachusetts under a noncancellable operating lease agreement for office and laboratory space. The rent payments for this facility escalate over the lease term and the Company expenses its obligations under this lease agreement on a straight-line basis over the term of the lease (see Note 8(a)).

(m) **CONCENTRATION OF RISK**

The Company relies on third parties to supply certain raw materials necessary to produce its drug candidates, including CUDC-101 and CUDC-907, for preclinical studies and clinical trials. There are a small number of suppliers for certain raw materials that the Company uses to manufacture its drug candidates.

(n) **NEW ACCOUNTING PRONOUNCEMENTS**

In June 2011, the FASB issued an amendment to the accounting guidance for presentation of comprehensive income. Under the amended guidance, a company may present the total of comprehensive income, the components of net income, and the components of other comprehensive

income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In either case, a company is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. Regardless of choice in presentation, the company is required to present on the face of the financial statements reclassification adjustments for items that are reclassified from other comprehensive income to net income in the statement(s) where the components of net income and the components of other comprehensive income are presented. For public companies, the amendment is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011, and shall be applied retrospectively, with the exception of reclassification adjustments which are currently deferred while the FASB redeliberates on this issue. Early adoption is permitted, and the Company adopted this pronouncement in the fourth quarter of 2011 and it has been applied to all years presented in the Company's consolidated financial statements. Other than a change in presentation, the adoption of this update did not have a material impact on the Company's consolidated financial statements.

In September 2011, the FASB issued an Accounting Standards Update ("ASU") which simplifies how companies test goodwill for impairment. The amendments permit an entity to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test described in goodwill accounting standard. The amendments are effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. Early adoption is permitted. The Company does not expect the new ASU to have a material effect on its financial position, results of operations or cash flows.

### **(3) RESEARCH AND DEVELOPMENT COLLABORATIONS**

#### **(a) GENENTECH, INC. JUNE 2003 COLLABORATION**

##### *(i) Agreement Summary*

In June 2003, the Company licensed its proprietary Hedgehog pathway technologies to Genentech for human therapeutic use. The primary focus of the collaborative research plan has been to develop molecules that inhibit the Hedgehog pathway for the treatment of various cancers. The collaboration is currently focused on the development of Erivedge™ (vismodegib/GDC-0449/RG3616), a small molecule Hedgehog pathway inhibitor for the treatment of certain solid tumor cancers that received FDA approval in January 2012 (see Note 13). Genentech is currently conducting a phase II clinical trial with Erivedge in operable basal cell carcinoma and several additional clinical trials are ongoing by third parties under collaboration agreements between Genentech and the National Cancer Institute as well as Genentech and third-party investigators.

Pursuant to the agreement, Genentech made an up-front payment of \$8,500,000, which consisted of a \$3,509,000 non-refundable license fee payment and \$4,991,000 in exchange for shares of the Company's common stock. Genentech also made license maintenance fee payments totaling \$4,000,000 over the first two years of the collaboration and agreed to make additional contingent cash payments, assuming specified clinical development and regulatory approval objectives are met. The Company is eligible to receive up to \$115,000,000 in contingent cash payments under the collaboration for the development of Erivedge or another small molecule Hedgehog pathway inhibitor, assuming the successful achievement by Genentech and Roche of specified clinical development and regulatory objectives, of which it has received \$32,000,000 as of December 31, 2011, consisting of:

- a \$3,000,000 payment filing an investigational new drug application in the U.S. for the treatment or prevention of any human cancer, including, but not limited to BCC, which the Company received in October 2006;
- a \$3,000,000 payment upon the administration of GDC-0449 in the first patient in the first phase II clinical trial for BCC, which the Company received in October 2007;

- a \$3,000,000 payment upon the administration of GDC-0449 in the first patient in the first phase II clinical trial for the first non-BCC solid tumor indication, which the Company received in May 2008;
- a \$3,000,000 payment upon the administration of GDC-0449 in the first patient in the first phase II clinical trial for the second non-BCC solid tumor indication, which the Company received in December 2008;
- a \$6,000,000 payment upon the administration of GDC-0449 in the first patient in the first phase II/III (pivotal phase II) clinical trial for BCC, which the Company received in March 2009;
- an \$8,000,000 payment upon the first NDA filing and FDA acceptance of GDC-0449 in the U.S., which the Company received in December 2011;
- a \$6,000,000 payment upon the first marketing authorization application filing and acceptance of GDC-0449 in a major market in the European Union, which the Company received in December 2011; and
- additional contingent payments assuming the successful achievement of additional specified clinical development and regulatory approval objectives (see Note 13).

In addition to these payments, the Company is also eligible to receive royalties on sales of any Hedgehog pathway inhibitor products that are successfully commercialized by Genentech and Roche. For Erivedge, Curis is entitled to a mid- to high-single digit royalty, which escalates within this range with increasing product sales. In certain specified circumstances, the royalty rate applicable to Erivedge may be decreased to a low- to mid-single digit royalty.

As a result of its licensing agreements with various universities, the Company is obligated to make payments to these university licensors when certain payments are received from Genentech. As of December 31, 2011, the Company has incurred aggregate expenses over the term of this collaboration of \$1,600,000, including \$700,000 and \$300,000 incurred in the years ended December 31, 2011 and 2009, respectively, in connection with its receipt of the \$32,000,000 in contingent cash payments from Genentech related to such university licensing agreement.

The collaboration provides for the development of small molecule and antibody Hedgehog pathway inhibitors for the treatment of cancer. The development of these programs is governed by a joint steering committee which is comprised of an equal number of representatives from both the Company and Genentech to oversee the research, development and commercialization and other efforts relating to these programs. Each member of the joint steering committee receives the right to cast one vote, but Genentech has the final decision making authority in most matters. The joint steering committee was required to meet on at least a quarterly basis until the filing of the first investigational new drug, or IND, application for a Hedgehog pathway inhibitor product candidate, which occurred in October 2006. After such filing, the joint steering committee shall meet as often as it deems necessary and shall exist as long as any compound under the collaboration is being developed or commercialized in accordance with the contract terms.

Unless terminated earlier, the agreement shall expire six months after the later of the expiration of Genentech's obligation to pay royalties to the Company under the agreement or such time as no activities have occurred under the agreement for a period of twelve months.

#### *(ii) Accounting Summary*

The Company considers its June 2003 arrangement with Genentech to be a revenue arrangement with multiple deliverables. The Company's deliverables under this collaboration include an exclusive license to its Hedgehog pathway inhibitor technologies, research and development services for the first two years of the collaboration, and participation on the joint steering committee. The Company applied the provisions of FASB Codification Topic 605-25, *Revenue Recognition, Multiple Element*



*Arrangement* to determine whether the performance obligations under this collaboration could be accounted for separately or should be accounted for as a single unit of accounting. The Company determined that the deliverables, specifically, the license, research and development services and steering committee participation, represented a single unit of accounting because the Company believes that the license, although delivered at the inception of the arrangement, did not have stand-alone value to Genentech without the Company's research and development services and steering committee participation. In addition, objective and reliable evidence of the fair value of the Company's research and development services and steering committee participation could not be determined. During 2007, the Company reassessed its participation on the joint steering committee and concluded that its participation in the joint steering committee had become inconsequential and perfunctory. Specifically, the Company believed that its participation on the joint steering committee was no longer essential to the development of Hedgehog pathway inhibitor compounds under the collaboration with Genentech, and the fair value or cost, if any, of completing the Company's obligation was insignificant in relation to the non-refundable up-front license fee and maintenance payments totaling \$7,509,000 received from Genentech that had been allocated to the single unit of accounting.

The Company received payments from Genentech totaling \$14,000,000 and \$6,000,000 during the years ended December 31, 2011 and 2009, respectively, for the achievement of certain clinical development objectives related to Erivedge described above. As the Company did not have any further performance obligations under the collaboration, the Company has recorded these amounts as revenue within "License Fees" in the Revenues section of its Consolidated Statement of Operations for the years ended December 31, 2011 and 2009, respectively. The Company did not receive any such payments for the year ended December 31, 2010. During the years ended December 31, 2011, 2010 and 2009, the Company also recorded revenue within "Research and development" of \$388,000, \$275,000 and \$229,000, respectively, as revenue related to expenses incurred on behalf of Genentech that were paid by the Company and for which Genentech is obligated to reimburse the Company. The Company will continue to recognize revenue for expense reimbursement as such reimbursable expenses are incurred, provided that the provisions of FASB Codification Topic 605-45 are met. As of December 31, 2011, the Company had recorded \$24,000 as amounts receivable from Genentech under this collaboration in "Accounts receivable" in the Company's Current Assets section of its Consolidated Balance Sheets.

**(b) DEBIOPHARM AUGUST 2009 LICENSE AGREEMENT**

*(i) Agreement Summary*

In August 2009, the Company entered into a license agreement with Debiopharm, pursuant to which the Company has granted to Debiopharm a worldwide, exclusive royalty-bearing license, with the right to grant sublicenses, to develop, manufacture, market and sell any product containing Curis' Hsp90 inhibitor technology, including its lead Hsp90 compound under development, CUDC-305, which Debiopharm has since renamed Debio 0932. Debiopharm has assumed all future development responsibility and all future costs related to the development, registration and commercialization of products under the agreement.

Pursuant to the terms of the agreement, the Company used its reasonable commercial efforts to transfer to Debiopharm know how, information and clinical materials necessary for Debiopharm to continue the development of products in accordance with the development plan outlined in the agreement, all of which were completed as of December 31, 2009. Furthermore, at no cost to Debiopharm, the Company provided a reasonable amount of technical, scientific and intellectual property support to the development plan, as requested by Debiopharm, during the first six months of the agreement.

Pursuant to the terms of the agreement, Debiopharm has agreed to undertake reasonable commercial efforts to implement the development plan in the timeframes described in the agreement in order to develop, register and commercialize the product in specified markets and will be solely responsible for

all the costs relating thereto. Debiopharm will retain final decision making authority on all development, commercialization, marketing, manufacturing and regulatory matters relating to the product.

As consideration for the exclusive license rights provided in the agreement, and subject to the terms of the agreement, Debiopharm has agreed to pay the Company up to an aggregate of \$90,000,000 assuming the successful achievement of specified clinical development and regulatory approval objectives consisting of:

- a \$2,000,000 up-front license fee, which the Company received in September 2009, upon the transfer to Debiopharm of certain information specified in the agreement;
- an \$8,000,000 payment upon the first regulatory approval in a major market country of an open investigational new drug application in the U.S. or a clinical trial application in Europe to initiate human clinical trials, which the Company received in March 2010;
- a \$3,000,000 payment upon the administration of Debio 0932 in the fifth patient in the first phase I clinical trial, which the Company received in August 2010; and
- additional contingent payments assuming the successful achievement of additional specified clinical development and regulatory approval objectives.

In addition, Debiopharm will pay the Company:

- a specified percentage of all sublicensing payments received by Debiopharm and its affiliates from sublicensees;
- a specified percentage of royalties Debiopharm and its affiliates receive from sublicensees; and
- a specified percentage of royalties on net sales of products by Debiopharm or its affiliates.

The agreement was effective as of August 5, 2009, and unless terminated earlier will expire, on a country-by-country basis, on the later of (i) the expiration of the last-to-expire valid claim of the Company's patents and joint patents relating to the products, and (ii) the 10<sup>th</sup> anniversary of the first commercial sale of the product in such country. Pursuant to the agreement, either party can terminate the agreement upon notice under prescribed circumstances, and the agreement specifies the consequences to each party for such early termination.

#### *(ii) Accounting Summary*

The Company considers its arrangement with Debiopharm to be a revenue arrangement with multiple deliverables, or performance obligations. The Company's substantive performance obligations under this collaboration included an exclusive license to its Hsp90 inhibitor technologies, a reasonable amount of technical, scientific and intellectual property support to the development plan, as requested by Debiopharm, during the first six months of the agreement and participation on a steering committee for which the Company received a \$2,000,000 up-front, nonrefundable license fee. The Company applied the provisions of FASB Codification Topic 605-25, *Revenue Recognition, Multiple Element Arrangements*, to determine whether the performance obligations under this collaboration could be accounted for separately or as a single unit or multiple units of accounting. The Company determined that these performance obligations represented a single unit of accounting, since, initially, the license does not have stand-alone value to Debiopharm without the Company's technical expertise and steering committee participation during the initial six-month period. In addition, objective and reliable evidence of the fair value of the Company's technical support and steering committee participation could not be determined.

The Company also provided clinical materials to Debiopharm for which the Company received additional consideration. The Company has determined that this deliverable is a separate unit of accounting from the license and related support, and consideration received would be recognized as

revenue in accordance with our revenue policy. During the year ended December 31, 2009, the Company recorded revenue within “Research and development” of \$532,000 related to such clinical materials expensed by the Company and purchased by Debiopharm.

At the time the agreement was entered into, the Company’s ongoing substantive performance obligations under this collaboration consisted of support to Debiopharm during the initial six months of the agreement and participation on a joint steering committee. The joint steering committee is comprised of four members, two from each company. Debiopharm retains final decision making authority on all development, commercialization, marketing, manufacturing and regulatory matters relating to any product candidates. The joint steering committee’s function is limited to facilitation of the collaboration, including providing a contractual mechanism of information exchange related to the product candidates being developed. The joint steering committee has no authority to make changes to the development plan, which can only be revised by Debiopharm upon advance notice to the Company. The Company has determined that its joint steering committee obligation is participatory for the initial six-month period in which it is also required to provide technical support. The Company’s main contribution during this time was to support Debiopharm’s preparation of the clinical trial application filing with regulatory authorities, which was filed in the fourth quarter of 2009. After January 2010, substantially all activities around the implementation and management of the development plan become the sole responsibility of Debiopharm, at which time, the Company believes that its role on the joint steering committee became protective and inconsequential or perfunctory. The Company has therefore estimated that its participation on the joint steering committee should only factor into the performance period as it relates to the six-month period in which the Company has a participatory role. Because the Company estimated that its level of effort would be consistent over the six-month term of the arrangement, the Company accounted for the arrangement under the proportional performance method.

The \$2,000,000 up-front fee was recognized ratably as the research and joint steering committee services were provided over the estimated six-month performance period, through January 2010, at a rate of \$333,000 per month. During the years ended December 31, 2010 and 2009, the Company recorded revenue of \$333,000 and \$1,667,000, respectively, related to the Company’s efforts under the Debiopharm arrangement, which was recorded in “License Fees” in the Company’s Revenues section of its Consolidated Statement of Operations.

The Company believes that contingent payments tied to preclinical, clinical development and drug approval objectives under this collaboration would not constitute substantive milestones since the successful achievement of these objectives would not meet each of the criteria set forth in the Company’s revenue recognition policy related to substantive milestones. For any contingent payments received by the Company subsequent to the conclusion of the performance period in January 2010, the Company would have no future deliverables under the agreement, and the Company would recognize such contingent payments as revenue at the time when the objectives are met and payable. The Company earned \$8,000,000 under this agreement in March 2010 upon acceptance by French regulatory authorities of Debiopharm’s clinical trial application for Hsp90 inhibitor, Debio 0932, and \$3,000,000 in July 2010 upon Debiopharm’s treatment of the fifth patient in its ongoing phase I clinical trial. The Company recorded \$11,000,000 as revenue within “License Fees” in the Revenues section of its Consolidated Statement of Operations for the year ended December 31, 2010 because the Company had no ongoing material performance obligations under the agreement. The Company did not receive any such payments for the year ended December 31, 2011.

**(c) THE LEUKEMIA & LYMPHOMA SOCIETY AGREEMENT**

In November 2011, the Company entered into an agreement under which The Leukemia & Lymphoma Society (LLS) will support the Company’s ongoing development of CUDC-907 for patients with B-cell lymphoma and multiple myeloma. Under the agreement, LLS will fund approximately 50% of the direct costs of the development of CUDC-907, up to \$4,000,000. Under certain conditions associated

with the successful partnering and/or commercialization of CUDC-907 in these indications, the Company may be obligated to make payments to LLS up to a maximum of \$10,000,000. The Company has not received any payments under this agreement to-date and expects that the first milestone could be achieved in the second half of 2012 as CUDC-907 nears IND filing. Additional milestones would be earned as the Company progresses CUDC-907 into a phase Ia clinical trial.

#### **(4) FORMER LICENSEES AND COLLABORATIONS**

##### **(a) MICROMET SETTLEMENT**

On February 4, 2010, the Company entered into a settlement, mutual release and termination agreement with Micromet, Inc. to resolve a claim filed by the Company relating to a June 2001 license agreement between the Company and Micromet's wholly owned subsidiary, Micromet AG, associated with the Company's single chain peptide technology. Under the June 2001 agreement, Micromet AG acquired from the Company certain intellectual property assets relating to single chain antibodies, including patents and license agreements. Pursuant to the settlement agreement, Micromet made a final payment of \$4,000,000 during the first quarter of 2010 to the Company in order to settle the dispute and discharge and terminate all future payment obligations that would have arisen under the June 2001 Agreement. The Company has recorded the \$4,000,000 within the "License fee" revenue line item in the Consolidated Statement of Operations for the year ended December 31, 2010. During the first quarter of 2010, the Company incurred approximately \$1,526,000 in legal fees and expenses through the settlement date. During the year ended December 31, 2009, the Company had incurred \$731,000 related to this matter. These costs are included within the "General and Administrative" expense line item of the Consolidated Statement of Operations for the respective periods.

#### **(5) STOCK PLANS AND STOCK BASED COMPENSATION**

As of December 31, 2011, the Company had two shareholder-approved, share-based compensation plans: the 2010 Stock Incentive Plan and the 2010 Employee Stock Purchase Plan. These plans were adopted by the board of directors in April 2010 and approved by shareholders in June 2010 as described below. In the first quarter of 2010, the Company's 2000 Stock Incentive Plan expired in accordance with its terms and its 2000 Director Stock Option Plan had no available shares remaining under the plan. No additional awards will be made under these plans, although all outstanding awards under these plans will remain in effect until they are exercised or they expire in accordance with their terms.

##### **2010 Stock Incentive Plan**

In April 2010, the Board of Directors adopted and, in June 2010, the stockholders approved, the 2010 Stock Incentive Plan, which permits the granting of incentive and non-qualified stock options and stock awards to employees, officers, directors, and consultants of the Company and its subsidiaries at prices determined by the Company's Board of Directors. The Company can issue up to 6,000,000 shares of its common stock pursuant to awards granted under the 2010 Stock Incentive Plan. Options become exercisable as determined by the Board of Directors and expire up to 10 years from the date of grant. The 2010 Stock Incentive Plan uses a "fungible share" concept under which each share of stock subject to awards granted as options and stock appreciation rights will cause one share per share under the award to be removed from the available share pool, while each share of stock subject to awards granted as restricted stock, restricted stock units, other stock-based awards or performance awards where the price charged for the award is less than 100% of the fair market value of the Company's common stock will cause 1.22 shares per share under the award to be removed from the available share pool. As of December 31, 2011, the Company had only granted options to purchase shares of the Company's common stock with an exercise price equal to the closing market price of the Company's common stock on the NASDAQ Global Market on the grant date. As of December 31, 2011, 4,367,000 shares remained available for grant under the 2010 Stock Incentive Plan.

During the year ended December 31, 2011, the Company's board of directors granted options to purchase 1,267,000 shares of the Company's common stock to officers and employees of the Company under the 2010 Stock Incentive Plan. These options vest over a four-year period and bear exercise prices that are equal to the closing market price of the Company's common stock on the NASDAQ Global Market on the respective grant dates.

During the year ended December 31, 2011, the Company's board of directors also granted options to its non-employee directors to purchase 260,000 shares of common stock under the 2010 Stock Incentive Plan. Of this amount, options to purchase 235,000 shares of common stock were fully vested on the January 7, 2011 grant date and options to purchase 25,000 shares of common stock will vest over a four-year period. All of these options bear exercise prices that are equal to the closing market price of the Company's common stock on the NASDAQ Global Market on the respective grant dates.

#### Employee and Director Grants

In determining the fair value of stock options, the Company uses the Black-Scholes option pricing model. The Black-Scholes option pricing model employs the following key assumptions for employee option grants issued in each of the following years:

	For the Year Ended December 31,		
	2011	2010	2009
Expected term (years)—Employees .....	6.0	6.0	6.0
Expected term (years)—Directors .....	6.0	6.0	6.0
Risk-free interest rate .....	1.2-2.5%	2.3-2.8%	2.1-2.6%
Expected volatility .....	73-76%	69-73%	67-82%
Expected dividend yield .....	None	None	None

The expected volatility is based on the annualized daily historical volatility of the Company's stock price through the end of the reporting period for a time period consistent with the expected term of a grant. Management believes that the historical volatility of the Company's stock price best represents the volatility of the stock price. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant. The Company does not anticipate declaring dividends in the foreseeable future.

The stock price volatility and expected terms utilized in the calculation involve management's best estimates at that time, both of which impact the fair value of the option calculated under the Black-Scholes methodology and, ultimately, the expense that will be recognized over the life of the option. GAAP also requires that the Company recognize compensation expense for only the portion of options that are expected to vest. Therefore, management calculated an estimated annual pre-vesting forfeiture rate that is derived from historical employee termination behavior since the inception of the Company, as adjusted. If the actual number of forfeitures differs from those estimated by management, additional adjustments to compensation expense may be required in future periods.

At December 31, 2011, the aggregate intrinsic value of employee options outstanding was \$27,912,000, of which \$23,055,000 related to exercisable options, and the weighted average remaining contractual life of vested stock options was 5.31 years. The weighted average grant-date fair values of stock options granted during the years ended December 31, 2011, 2010 and 2009 were \$1.72, \$1.46 and \$0.82, respectively. As of December 31, 2011, there was approximately \$2,724,000, including the impact of estimated forfeitures, of unrecognized compensation cost related to unvested employee stock option awards outstanding under the Company's 2000 and 2010 Stock Incentive Plans that is expected to be recognized as expense over a weighted average period of 2.5 years. The intrinsic value of employee stock options exercised during the years ended December 31, 2011, 2010 and 2009 were \$2,129,000, \$154,000 and \$515,000, respectively. The total fair value of vested stock options for the years ended December 31, 2011, 2010 and 2009 were \$1,504,000, \$2,219,000 and \$1,593,000, respectively.

### *Non-Employee Grants*

The Company has periodically granted stock options and unrestricted stock awards to consultants for services. During the year ended December 31, 2011, the Company issued options to purchase a total of 125,000 shares of common stock to the chairman of the Company's Clinical and Scientific Advisory Board. These options were issued pursuant to the 2010 Stock Incentive Plan at an exercise price equal to the fair market value of the common stock on the dates of grant and will vest over a four-year period from the respective date of grant. Should the Company or the consultant terminate the consulting agreement, any unvested options will be cancelled. Unvested non-employee options are marked-to-market, which means that as the Company's stock price fluctuates, the related expense either increases or decreases. The Company recognized expense of \$130,281 and \$104,437 related to non-employee stock options and stock awards for the years ended December 31, 2011 and 2009, respectively. The Company reversed expense of \$11,968 related to non-employee stock options and stock awards for the years ended December 31, 2010.

A summary of stock option activity under 2010 Stock Incentive Plan, the 2000 Stock Incentive Plan and the 2000 Director Stock Option Plan is summarized as follows:

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price per Share</u>
Outstanding, December 31, 2010 (9,524,572 exercisable at weighted average price of \$2.20 per share) .....	11,537,750	\$2.12
Granted .....	1,652,000	2.66
Exercised .....	(1,146,508)	1.70
Cancelled .....	<u>(949,001)</u>	3.48
Outstanding, December 31, 2011 (8,888,033 exercisable at weighted average price of \$2.06 per share) .....	<u>11,094,241</u>	<u>\$2.13</u>
Vested and unvested expected to vest .....	11,068,727	\$2.13

The table below summarizes options outstanding and exercisable at December 31, 2011:

<u>Exercise Price Range</u>	<u>Options Outstanding</u>			<u>Options Exercisable</u>	
	<u>Number of Shares</u>	<u>Weighted Average Remaining Contractual Life (in years)</u>	<u>Weighted Average Exercise Price per Share</u>	<u>Number of Shares</u>	<u>Weighted Average Exercise Price per Share</u>
\$0.79 - \$ 1.39 .....	3,339,163	5.78	\$1.19	3,039,311	\$1.21
1.43 - 2.15 .....	3,652,470	5.69	1.70	2,771,277	1.57
2.27 - 3.98 .....	3,229,608	5.25	2.91	2,199,445	2.85
4.03 - 5.60 .....	873,000	2.51	4.63	873,000	4.63
	<u>11,094,241</u>	<u>5.34</u>	<u>\$2.13</u>	<u>8,883,033</u>	<u>\$2.06</u>

### **2010 Employee Stock Purchase Plan**

In April 2010, the Board of Directors adopted and, in June 2010, the stockholders approved, the 2010 Employee Stock Purchase Plan, or the ESPP. The Company has reserved 500,000 of its shares of common stock for issuance under the ESPP. Eligible employees may purchase shares of the Company's common stock at 85% of the lower closing market price of the common stock at the beginning or ending date of the purchase period, as defined. The Company has two six-month purchase periods per year. As of December 31, 2011, 162,834 shares were issued under the ESPP, of which 109,362 were issued during 2011. As of December 31, 2011, there were 337,166 shares available for future purchase under the ESPP.

For the years ended December 31, 2011, 2010 and 2009, the Company recorded compensation expense related to its ESPP and calculated the fair value of shares expected to be purchased under the ESPP using the Black-Scholes models with the following assumptions:

	For the Year Ended December 31,		
	2011	2010	2009
Compensation expense recognized under ESPP . . .	\$ 94,529	\$ 51,000	\$ 72,000
Expected term . . . . .	6 months	6 months	6 months
Risk-free interest rate . . . . .	0.1-0.2%	0-0.2%	0-0.3%
Volatility . . . . .	75-85%	85-120%	70-86%
Dividends . . . . .	None	None	None

Stock-based compensation for employee and director stock option grants for the years ended December 31, 2011, 2010 and 2009 of \$1,641,830, \$1,979,090 and \$1,749,798, respectively, was calculated using the above valuation models and has been included in the Company's results of operations.

Certain stock options to purchase a total of 816,500 shares of the Company's common stock were issued to employees of the Company in 2008 and 2007 in which vesting was tied to a performance condition. These options immediately vested upon the consummation of a collaboration, licensing or other similar agreement regarding programs under the Company's network-targeted cancer programs that included an up-front cash payment of at least \$10,000,000 excluding any equity investment in the Company and subject to the employee's continued employment. The Company's Compensation Committee of its Board of Directors determined that the performance condition underlying these options was met in conjunction with the Debiopharm licensing agreement (see Note 3(b)). Receipt of the March 2010 payment from Debiopharm resulted in the immediate vesting of these options and the Company recorded approximately \$485,000 in stock compensation expense related to the acceleration of vesting of the underlying options during the year ended December 31, 2010.

#### **Total Stock-Based Compensation Expense**

For the years ended December 31, 2011, 2010 and 2009, the Company recorded employee and non-employee stock-based compensation expense to the following line items in its Costs and Expenses section of the Consolidated Statements of Operations and Comprehensive Loss:

	For the Year ended December 31,		
	2011	2010	2009
Research and development expenses . . . . .	\$ 723,634	\$ 663,286	\$ 688,210
General and administrative expenses . . . . .	1,048,477	1,303,836	1,166,025
Total stock-based compensation expense . . . . .	<u>\$1,772,111</u>	<u>\$1,967,122</u>	<u>\$1,854,235</u>

No income tax benefits have been recorded for the years ended December 31, 2011, 2010 or 2009, as the Company has recorded a full valuation allowance and management has concluded that it is not likely that the net deferred tax assets will be realized (see Note 10).

## (6) PROPERTY AND EQUIPMENT

Property and equipment consist of the following:

	December 31,	
	2011	2010
Laboratory equipment, computers and software .....	\$ 2,503,832	\$ 2,679,634
Leasehold improvements .....	62,621	17,938
Office furniture and equipment .....	281,445	307,548
	2,847,898	3,005,120
Less—Accumulated depreciation and amortization .....	(2,392,168)	(2,702,399)
Total .....	<u>\$ 455,730</u>	<u>\$ 302,721</u>

The Company recorded depreciation and amortization expense of \$107,396, \$686,495 and \$751,213 for the years ended December 31, 2011, 2010 and 2009, respectively.

During the years ended December 31, 2011 and 2010, the Company identified certain of its fully depreciated assets that were no longer being used. As a result, the Company wrote off gross assets and related accumulated depreciation, totaling \$418,000 and \$7,038,000, for the years ended December 31, 2011 and 2010, respectively. Of the fully depreciated assets written off during the year ended December 31, 2010, \$6,407,000 related to leasehold improvements and fixtures at the 45 Moulton Street facility that the Company vacated in December 2010 at the end of its lease term.

## (7) ACCRUED LIABILITIES

Accrued liabilities consist of the following:

	December 31,	
	2011	2010
Accrued compensation .....	\$1,065,570	\$539,325
Professional fees .....	190,500	142,500
Facility-related costs .....	—	33,699
Other .....	166,037	139,081
Total .....	<u>\$1,422,107</u>	<u>\$854,605</u>

## (8) COMMITMENTS

### (a) OPERATING LEASES

Effective September 16, 2010, the Company entered into a lease agreement with the Trustees of Lexington Office Realty Trust pursuant to which the Company agreed to lease 24,529 square feet of property to be used for office, research and laboratory located at 4 Maguire Road in Lexington, Massachusetts. The Company lease for its prior headquarters at 45 Moulton Street, Cambridge, Massachusetts expired on December 31, 2010.

The term of the 4 Maguire Road lease agreement commenced on December 1, 2010, and expires on January 31, 2018. The Company has the option to extend the term for one additional five-year period upon the Company's written notice to the lessor at least one year and no more than 18 months in advance of the extension. The Company also has the option to terminate the lease agreement after three years, referred to as the early termination option, upon the Company's written notice to the lessor no later than the second anniversary of the rent commencement date as defined in the lease agreement. Concurrently with such notice, the Company is required to pay a termination fee to the lessor equal to the sum of two months base rent at the rate for the third year of the term and 65.46% of the value of certain transaction expenses incurred by the lessor. The maximum fee for exercising this early termination option is \$772,000.



The total cash obligation for the base rent over the initial term of the lease agreement is approximately \$4,401,000. In addition to the base rent, the Company is also responsible for its share of operating expenses and real estate taxes, in accordance with the terms of the lease agreement. The Company has provided a security deposit to the lessor in the form of an irrevocable letter of credit in the original amount of \$277,546, which was reduced to \$235,914 during 2011 in accordance with the terms of the Company's lease. These amounts have been classified as the restricted long-term investment in the Company's Consolidated Balance Sheet as of December 31, 2011 and 2010. The security deposit may be reduced by up to an additional \$83,264 over time in accordance with the terms of the lease agreement. The lessor paid \$789,000 for certain upgrades and repairs that were made to the leased property prior to the commencement date. The Company has not recognized these improvements as its assets.

If the Company is considered in default under the terms of the lease agreement and fails to cure such default in the applicable time period, the lessor may terminate the lease agreement and the Company will be required to pay the difference between the remaining rent payments through the expiration of the lease agreement and any rental income from reletting the leased property over such time period, after deducting any expenses incurred in connection with such reletting. Circumstances which may be considered a default under the lease agreement include the failure to timely pay any rent obligations and the filing by the Company of a petition for liquidation or reorganization under bankruptcy law.

The Company's remaining operating lease commitments for all leased facilities with an initial or remaining term of at least one year are as follows:

**Year Ending December 31,**

2012 .....	578,000
2013 .....	602,000
2014 .....	627,000
2015 .....	651,000
2016 .....	676,000
Thereafter .....	758,000
Total minimum payments .....	<u>\$3,892,000</u>

Rent expense for all operating leases was \$614,000, \$827,000 and \$776,000 for the years ended December 31, 2011, 2010 and 2009, respectively.

**(b) LICENSE AGREEMENTS**

In exchange for the right to use licensed technology in its research and development efforts, the Company has entered into various license agreements. These agreements generally stipulate that the Company pay an annual license fee and is obligated to pay royalties on future revenues, if any, resulting from use of the underlying licensed technology. Such revenues may include, for example, up-front license fees, contingent payments upon collaborators' achievement of development and regulatory objectives, and royalties. In addition, some of the agreements commit the Company to make contractually defined payments upon the attainment of scientific or clinical milestones and the Company may also be required to issue up to a total of 200,000 shares of its common stock under agreements with two of its university licensors. The Company expenses these payments as incurred and expects to expense royalty payments as related future product sales or royalty revenues, if any, are recorded. The Company accrues expenses for scientific and clinical objectives over the period that the work required to meet the respective objective is completed, provided that the Company believes that the achievement of such objective is probable (see Note 13). The Company incurred license fee expenses within the "Research and development" line item of its "Costs and expenses" section of its Consolidated Statement of Operations for the years ended December 31, 2011, 2010 and 2009, of \$908,000, \$243,000 and \$193,000, respectively.

## **(9) COMMON STOCK AND WARRANT LIABILITY**

### ***2011 At Market Issuance Sales Agreement***

On June 13, 2011, the Company entered into an At Market Issuance Sales Agreement, or ATM agreement, with McNicoll, Lewis & Vlak LLC, or MLV, pursuant to which the Company may issue and sell from time to time through MLV shares of its common stock, \$0.01 par value per share, with an aggregate offering price of up to \$20,000,000. Upon delivery of a placement notice and subject to the terms and conditions of the ATM agreement, MLV may sell the common stock by methods deemed to be an “at-the-market” offering as defined in Rule 415 of the Securities Act of 1933, including without limitation sales made directly on The NASDAQ Global Market, on any other existing trading market for the common stock or through a market maker. With the Company’s prior written approval, MLV may also sell the common stock by any other method permitted by law, including in privately negotiated transactions. The Company or MLV may suspend or terminate the offering of common stock upon notice and subject to other conditions. Unless earlier terminated, the ATM agreement will expire on the earlier of June 13, 2013 or upon the issuance and sale of common stock for an aggregate of \$20,000,000 under the agreement. MLV will act as sales agent on a commercially reasonable best efforts basis consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of NASDAQ. The Company will pay MLV a commission equal to 3.0% of the gross sales price per share sold. The Company has agreed to provide indemnification and contribution to MLV against certain civil liabilities, including liabilities under the Securities Act. Since the inception of the ATM agreement, the Company has sold 104,118 shares of common stock under the ATM agreement resulting in gross proceeds of \$416,965. Total offering expenses, including MLV’s commission, incurred related to the ATM agreement through December 31, 2011 were approximately \$128,155, which offset the gross proceeds.

### ***2010 Registered Direct Offering***

On January 27, 2010, the Company completed a registered direct offering of 6,449,288 units with each unit consisting of (i) one share of the Company’s common stock and (ii) one warrant to purchase 0.25 of one share of common stock at a purchase price of \$2.52 per unit. The Company received net proceeds from the sale of the units, after deducting offering expenses, of approximately \$14,942,000 during the year ended December 31, 2010.

In connection with this offering, the Company issued warrants to purchase an aggregate of 1,612,322 shares of common stock. The warrants have an initial exercise price of \$3.55 per share and a five-year term. The warrants include certain protective features for the benefit of the warrant holder, including an anti-dilution adjustment clause and a possible cash-settlement option in the event of a change of control until the later to occur of (i) two years from the date of original issuance of the warrant and (ii) the date upon which Genentech or Roche submits a new drug application (NDA) for Erivedge (vismodegib) which occurred in September 2011. As such, the cash-settlement option upon a change of control expired on January 27, 2012 and has no additional value to the warrant holders.

Due to the original terms, the warrants were deemed to be a liability and, therefore, the fair value of the warrants was recorded as a liability in the Consolidated Balance Sheets as of December 31, 2011 and 2010. The Company estimated that the fair value of the warrants at issuance was \$2,180,555 using a Black-Scholes option pricing model under various probability-weighted outcomes which take into consideration the protective, but limited, cash-settlement feature of the warrants with the following assumptions assigned to the varying outcomes: expected volatilities of 69.8% and 80%, risk free interest rates ranging from 1.42% to 2.38%, expected lives of three to five years, and no dividends.

The Company estimated that the fair value of the warrants at December 31, 2011 was \$4,361,168 using this same model with the following assumptions: expected volatility of 78%, a risk free interest rate of 0.4%, expected lives of three years, and no dividends. The Company estimated that the fair value of the warrants at December 31, 2010 was \$1,604,742 using this same model with the following assumptions

assigned to the varying outcomes: expected volatilities of 77.1% and 91.5%, risk free interest rates ranging from 1.0% to 1.6%, expected lives of three to four years and no dividends. The warrants will be revalued each reporting period with updated assumptions, and the resulting change in fair value of the warrant liability will be recognized in the Consolidated Statement of Operations and Comprehensive Loss.

The Company recorded other expense of \$2,756,426 and other income of \$575,813 for the years ended December 31, 2011 and 2010, respectively, as a result of a change in the fair value of the warrant liability that was primarily due to changes in the Company's stock price during the respective reporting periods. As of December 31, 2011, warrants to purchase an aggregate of 1,610,818 shares of common stock are the only remaining warrants outstanding.

### ***2007 Private Placement Offering***

As of December 31, 2009, the Company had warrants outstanding to purchase an aggregate of 1,742,671 shares of its common stock at an exercise price of \$1.02 per share under its August 2007 private placement, all of which had been accounted for within stockholders' equity. During the year ended December 31, 2010, the Company received proceeds of \$1,777,524 upon the exercise of all of these remaining outstanding warrants. During the year ended December 31, 2009, certain of the warrants issued under the August 2007 private placement were exercised to purchase an aggregate of 3,028,188 shares of the Company's common stock, providing approximately \$3,088,752 in cash proceeds to the Company.

## **(10) INCOME TAXES**

For the years ended December 31, 2011, 2010 and 2009, the Company did not record any federal or state income tax expense given its continued operating losses. The Company received federal tax grants of \$489,000 for the year ended December 31, 2010 under the Patient Protection and Affordable Care Act of 2010. The Company did not have any ongoing obligations under these awards and it does not expect to receive any future payments related to these grants. As a result, the Company recorded the proceeds as "Other income" in its Consolidated Statement of Operations for the year ended December 31, 2010. The grant proceeds were non-taxable on the federal and state level.

The provision for income taxes for continuing operations was at rates different from the U.S. federal statutory income tax rate for the following reasons:

	<b>For the Year Ended December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
Statutory federal income tax rate .....	34.0%	34.0%	34.0%
State income taxes, net of federal benefit .....	5.1%	5.0%	6.0%
Research and development tax credits .....	5.4%	8.7%	2.6%
Deferred compensation .....	(0.4%)	(4.0%)	(1.6%)
NOL expirations .....	(17.3%)	(58.4%)	(36.1%)
Effect of change in state rate .....	—%	—%	(11.9%)
Other .....	(1.9%)	(1.5%)	(1.5%)
Net (increase) decrease in valuation allowance .....	(24.9%)	16.2%	8.5%
Effective income tax rate .....	<u>—%</u>	<u>—%</u>	<u>—%</u>

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using future expected enacted rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized.

The principle components of the Company's deferred tax assets at December 31, 2011 and 2010, respectively are as follows:

	December 31,	
	2011	2010
Deferred Tax Assets:		
Net operating loss carryforwards .....	\$ 70,767,000	\$ 69,997,000
Research and development tax credit		
carryforwards .....	10,661,000	10,296,000
Depreciation and amortization .....	175,000	233,000
Capitalized research and development		
expenditures .....	22,820,000	22,419,000
Deferred revenue .....	—	—
Impairment of investments .....	108,000	102,000
Stock options .....	2,433,000	2,594,000
Accrued expenses and other .....	1,823,000	699,000
Total Gross Deferred Tax Asset .....	108,787,000	106,340,000
Valuation Allowance .....	(108,787,000)	(106,340,000)
Net Deferred Tax Asset .....	\$ —	\$ —

The classification of the above deferred tax assets is as follows:

	December 31,	
	2011	2010
Deferred Tax Assets:		
Current deferred tax assets .....	\$ 45,000	\$ 693,000
Non-current deferred tax assets .....	108,742,000	105,647,000
Valuation Allowance .....	(108,787,000)	(106,340,000)
Net Deferred Tax Asset .....	\$ —	\$ —

As of December 31, 2011, the Company had federal and state net operating losses, or NOLs, of \$200,976,000 and \$46,115,000, respectively, and federal and state research and experimentation credit carryforwards of approximately \$8,640,000 and \$3,063,000, respectively, which will expire at various dates starting in 2011 through 2031. The Company had \$4,105,000 of federal net operating losses generated in 1996 and \$6,059,000 of Massachusetts net operating losses generated in 2006 that expired in 2011. As required by GAAP, the Company's management has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, and has determined that it is not more likely than not that the Company will recognize the benefits of the deferred tax assets. Accordingly, a valuation allowance of approximately \$108,787,000 has been established at December 31, 2011. The benefit of deductions from the exercise of stock options is included in the NOL carryforwards. The benefit from these deductions will be recorded as a credit to additional paid-in capital if and when realized through a reduction of cash taxes.

Utilization of the NOL and R&D credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company has not completed a study to assess whether a change of control has occurred or whether there have been multiple changes of control since the Company's formation because the Company continues to maintain a full valuation allowance on its NOL and R&D credit carryforwards. In addition, there could be additional ownership changes in the future, which may result in additional limitations in the utilization of the carryforward NOLs and credits, and the Company does not expect to have any taxable income for the foreseeable future.

An individual tax position must satisfy for some or all of the benefits of that position to be recognized in a company's financial statements. At December 31, 2011 and 2010, the Company had no unrecognized tax benefits. The Company has not, as yet, conducted a study of its research and development credit carryforwards. This study may result in an adjustment to the Company's research and development credit carryforwards, however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position under Topic 740. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheet or statement of operations if an adjustment were required.

The tax years 1997 through 2011 remain open to examination by major taxing jurisdictions to which the Company is subject, which are primarily in the United States ("U.S."), as carryforward attributes generated in years past may still be adjusted upon examination by the Internal Revenue Service ("IRS") or state tax authorities if they have or will be used in a future period. The Company is currently not under examination by the Internal Revenue Service or any other jurisdictions for any tax years. The Company recognizes both accrued interest and penalties related to unrecognized benefits in income tax expense. The Company has not recorded any interest and penalties on any unrecognized tax benefits since its inception.

#### (11) RETIREMENT SAVINGS PLAN

The Company has a 401(k) retirement savings plan covering substantially all of the Company's employees. Matching Company contributions are at the discretion of the Board of Directors. For the years ended December 31, 2011, 2010 and 2009, the Board of Directors authorized matching contributions of \$145,000, \$103,000 and \$249,000, respectively.

#### (12) SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

The following are selected quarterly financial data for the years ended December 31, 2011 and 2010:

	Quarter Ended			
	March 31, 2011	June 30, 2011	September 30, 2011	December 31, 2011
Revenues .....	\$ 133,538	\$ 392,867	\$ 147,122	\$14,089,053
(Loss) income from operations .....	(5,332,310)	(4,618,965)	(4,816,335)	7,565,107
Net (loss) income .....	(6,800,151)	(4,914,064)	(4,206,555)	6,061,875
Net (loss) income per common share (basic) .....	\$ (0.09)	\$ (0.06)	\$ (0.05)	\$ 0.08
Net (loss) income per common share (diluted) .....	\$ (0.09)	\$ (0.06)	\$ (0.05)	\$ 0.07
Weighted average common shares (basic) .....	75,825,801	76,378,369	76,543,074	76,649,034
Weighted average common shares (diluted) .....	75,825,801	76,378,369	76,543,074	81,354,223
	March 31, 2010	June 30, 2010	September 30, 2010	December 31, 2010
Revenues .....	\$12,558,334	\$ 98,634	\$ 3,242,310	\$ 100,287
Income (loss) from operations .....	5,664,085	(3,926,485)	(1,764,985)	(5,610,359)
Net income (loss) .....	4,784,265	(2,097,987)	(1,514,799)	(5,606,789)
Net income (loss) per common share (basic) .....	\$ 0.07	\$ (0.03)	\$ (0.02)	\$ (0.07)
Net income (loss) per common share (diluted) .....	\$ 0.06	\$ (0.03)	\$ (0.02)	\$ (0.07)
Weighted average common shares (basic) .....	72,889,133	75,617,858	75,623,465	75,668,337
Weighted average common shares (diluted) .....	76,282,898	75,617,858	75,623,465	75,668,337

The net income amount presented above for the quarter ending December 31, 2011 includes \$14,000,000 of license revenue recognized under the June 2003 license agreement with Genentech. Dilutive securities of 4,652,519 shares related to stock options and 52,670 shares related to warrants have been included in the weighted average common shares (diluted) for the quarter ended December 31, 2011

The net loss amount presented above for the quarter ending December 31, 2010 includes \$489,000 of other income which represents federal tax grants that the Company received under the Patient Protection and Affordable Care Act of 2010 to support ongoing clinical and preclinical development activities related to its CUDC-101 and our other network-targeted cancer programs. The Company does not have any ongoing obligations under these awards and it does not expect to receive any future payments related to these grants.

### **(13) SUBSEQUENT EVENTS**

In January 2012, the FDA approved Genentech's New Drug Application for the Erivedge™ capsule for the treatment of adults with basal cell carcinoma that has spread to other parts of the body or that has come back after surgery or that their healthcare provider decides cannot be treated with surgery or radiation. Erivedge is being developed and will be commercialized by Roche and Genentech, a member of the Roche Group, under a collaboration agreement between the Company and Genentech (see Note 3(a)). As a result of the FDA's approval of Erivedge in this indication, the Company earned a \$10,000,000 payment from Genentech and is also entitled to receive royalties on future sales of the product. In addition, the Company is obligated to pay \$500,000 in sublicense fees to third-parties upon receipt of this payment and a total of 5% of any royalties received from the sale of Erivedge.

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls & Procedures*

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2011. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2011, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective.

Management’s report on internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, is included in Item 8 of this annual report on Form 10-K and is incorporated herein by reference.

*Changes in Internal Control Over Financial Reporting*

No changes in our internal control over financial reporting occurred during the fourth quarter of the fiscal year ended December 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None.

## **PART III**

### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

Information concerning directors that is required by this Item 10 is set forth in our proxy statement for our 2012 annual meeting of stockholders under the headings “Directors and Nominees for Director,” “Board Committees” and “Section 16(a) Beneficial Ownership Reporting Compliance,” which information is incorporated herein by reference. The information concerning our code of ethics is set forth in our proxy statement under the heading “Code of Business Conduct and Ethics.” The name, age, and position of each of our executive officers is set forth under the heading “Executive Officers of the Registrant” in Part I of this Annual Report on Form 10-K, which information is incorporated herein by reference.

### **ITEM 11. EXECUTIVE COMPENSATION**

Information required by this Item 11 is set forth in our proxy statement for our 2012 annual meeting of stockholders under the headings “Executive and Director Compensation and Related Matters,” “Compensation Committee Interlocks and Insider Participation” and “Compensation Committee Report” which information is incorporated herein by reference.

### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

Information required by this Item 12 relating to security ownership of certain beneficial owners and management is contained in our 2012 proxy statement under the caption “Security Ownership of Certain Beneficial Owners and Management” and is incorporated herein by reference. Information required by this Item 12 relating to securities authorized for issuance under equity compensation plans is contained in our 2012 proxy statement under the caption “Executive and Director Compensation and Related Matters—Securities Authorized for Issuance Under Equity Compensation Plans” and is incorporated herein by reference.

### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

Information required by this Item 13 is set forth in our proxy statement for our 2012 annual meeting of stockholders under the headings “Policies and Procedures for Related Person Transactions,” “Determination of Independence” and “Board Committees,” which information is incorporated herein by reference.

### **ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

Information required by this Item 14 is set forth in our proxy statement for our 2012 annual meeting of stockholders under the heading “Independent Registered Public Accounting Firm’s Fees and Other Matters,” which information is incorporated herein by reference.



## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

#### (a)(1) *Financial Statements.*

	<u>Page number in this report</u>
<b><u>Curis, Inc. and Subsidiaries</u></b>	
Report of Independent Registered Public Accounting Firm .....	71
Consolidated Balance Sheets as of December 31, 2011 and 2010 .....	72
Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2011, 2010 and 2009 .....	73
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2011, 2010 and 2009 .....	74
Consolidated Statements of Cash Flows for the Years Ended December 31, 2011, 2010 and 2009 .....	75
Notes to Consolidated Financial Statements .....	76

#### (a)(2) *Financial Statement Schedules.*

All schedules are omitted because they are not applicable or the required information is shown in the Financial Statement or Notes thereto.

(a)(3) *List of Exhibits.* The list of Exhibits filed as a part of this annual report on Form 10-K is set forth on the Exhibit Index immediately preceding such Exhibits, and is incorporated herein by reference.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CURIS, INC.

By: /s/ DANIEL R. PASSERI  
**Daniel R. Passeri**  
**President and Chief Executive Officer**

Date: February 29, 2012

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ DANIEL R. PASSERI</u> <b>Daniel R. Passeri</b>	President, Chief Executive Officer and Director (Principal Executive Officer)	February 29, 2012
<u>/s/ MICHAEL P. GRAY</u> <b>Michael P. Gray</b>	Chief Operating Officer and Chief Financial Officer (Principal Financial and Accounting Officer)	February 29, 2012
<u>/s/ JAMES R. MCNAB, JR.</u> <b>James R. McNab, Jr.</b>	Chairman of the Board of Directors	February 29, 2012
<u>/s/ SUSAN B. BAYH</u> <b>Susan B. Bayh</b>	Director	February 29, 2012
<u>/s/ MARTYN D. GREENACRE</u> <b>Martyn D. Greenacre</b>	Director	February 29, 2012
<u>/s/ KENNETH I. KAITIN</u> <b>Kenneth I. Kaitin</b>	Director	February 29, 2012
<u>/s/ ROBERT MARTELL</u> <b>Robert Martell</b>	Director	February 29, 2012
<u>/s/ MARC RUBIN</u> <b>Marc Rubin</b>	Director	February 29, 2012
<u>/s/ JAMES R. TOBIN</u> <b>James R. Tobin</b>	Director	February 29, 2012

## EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference			
		Form	SEC Filing Date	Exhibit Number	Filed with this 10-K
<b><i>Articles of Incorporation and By-laws</i></b>					
3.1	Restated Certificate of Incorporation of Curis, Inc.	S-4/A (333-32446)	06/19/00	3.3	
3.2	Certificate of Designations of Curis, Inc.	S-3(333-50906)	08/10/01	3.2	
3.3	Amended and Restated By-laws of Curis, Inc.	S-1(333-50906)	11/29/00	3.2	
3.4	Amendment to Amended and Restated By-laws of Curis, Inc.	8-K	09/24/07	3.1	
<b><i>Instruments defining the rights of security holders, including indentures</i></b>					
4.1	Form of Curis Common Stock Certificate	10-K	03/01/04	4.1	
<b><i>Material contracts—Management Contracts and Compensatory Plans</i></b>					
#10.1	Employment Agreement, dated as of September 18, 2007, between Curis and Daniel R. Passeri	8-K	09/24/07	10.1	
#10.2	Amendment to Employment Agreement, dated as of October 27, 2008, to the employment agreement dated September 18, 2007, by and between Curis and Daniel R. Passeri	10-Q	10/28/08	10.1	
#10.3	Amendment to Employment Agreement, dated as of December 10, 2010, to the employment agreement dated September 18, 2007, by and between Curis and Daniel R. Passeri	10-K	03/08/11	10.3	
#10.4	Offer Letter, dated as December 10, 2003, between Curis and Michael P. Gray	10-K	03/01/04	10.4	
#10.5	Amendment to Offer Letter, dated as of October 31, 2006, to the offer letter dated December 10, 2003, by and between Curis and Michael P. Gray	8-K	11/02/06	10.3	
#10.6	Amendment to Offer Letter, dated as of October 27, 2008, to the offer letter dated December 10, 2003, by and between Curis and Michael P. Gray	10-Q	10/28/08	10.2	
#10.7	Amendment to Offer Letter, dated as of December 10, 2010, to the offer letter dated December 10, 2003, by and between Curis and Michael P. Gray	10-K	03/08/11	10.7	

<u>Exhibit No.</u>	<u>Description</u>	<u>Incorporated by Reference</u>			
		<u>Form</u>	<u>SEC Filing Date</u>	<u>Exhibit Number</u>	<u>Filed with this 10-K</u>
#10.08	Offer Letter, dated January 11, 2001, by and between Curis and Mark W. Noel	10-K	03/02/07	10.6	
#10.09	Amendment to Offer Letter, dated as of October 31, 2006, to the offer letter dated January 11, 2001, by and between Curis and Mark W. Noel	8-K	11/02/06	10.4	
#10.10	Amendment to Offer Letter, dated as of October 27, 2008, to the offer letter dated January 11, 2001, by and between Curis and Mark W. Noel	10-Q	10/28/08	10.4	
#10.11	Amendment to Offer Letter, dated as of December 10, 2010, to the offer letter dated January 11, 2001, by and between Curis and Mark W. Noel	10-K	03/08/11	10.16	
#10.12	Offer Letter, dated March 21, 2008, by and between Curis and Mitchell Keegan	8-K	06/04/10	10.4	
#10.13	Amendment to Offer Letter, dated as of June 3, 2010, to the offer letter dated March 21, 2008, by and between Curis and Mitchell Keegan	8-K	06/04/10	10.5	
#10.14	Amendment to Offer Letter, dated as of December 10, 2010, to the offer letter dated March 21, 2008, by and between Curis and Mitchell Keegan	10-K	03/08/11	10.19	
#10.15	Employment Agreement, dated November 7, 2011, by and between Curis and Maurizio Voi	8-K	11/10/11	10.1	
#10.16	Agreement for Service as Chairman of the Board of Directors, between Curis, Inc. and James McNab, dated as of June 1, 2005	8-K	06/07/05	10.1	
#10.17	Form of Indemnification Agreement, between Curis, Inc. and each member of the Board of Directors	10-K	03/08/11	10.23	
#10.18	Curis 2000 Stock Incentive Plan	S-4/A (333-32446)	05/31/00	10.71	
#10.19	Curis 2000 Director Stock Option Plan	S-4/A (333-32446)	05/31/00	10.72	
#10.20	Curis 2000 Employee Stock Purchase Plan	S-4/A (333-32446)	05/31/00	10.73	
#10.21	Form of Incentive Stock Option Agreement granted to directors and named executive officers under Curis' 2000 Stock Incentive Plan	10-Q	10/26/04	10.2	
#10.22	Form of Non-statutory Stock Option Agreement granted to directors and named executive officers under Curis' 2000 Stock Incentive Plan	10-Q	10/26/04	10.3	

Exhibit No.	Description	Incorporated by Reference			
		Form	SEC Filing Date	Exhibit Number	Filed with this 10-K
#10.23	Form of Non-statutory Stock Option Agreement granted to non-employee directors under Curis' 2000 Director Stock Option Plan	10-Q	10/26/04	10.4	
#10.24	Curis 2010 Stock Incentive Plan	Def 14A	04/16/10	Exhibit A	
#10.25	Curis 2010 Employee Stock Purchase Plan	Def 14A	04/16/10	Exhibit B	
#10.26	Form of Incentive Stock Option Agreement granted to directors and named executive officers under Curis' 2010 Stock Incentive Plan	8-K	06/04/10	10.1	
#10.27	Form of Non-Statutory Stock Option Agreement granted to directors and named executive officers under Curis' 2010 Stock Incentive Plan	8-K	06/04/10	10.2	
#10.28	Form of Restricted Stock Agreement granted to directors and named executive officers under Curis' 2010 Stock Incentive Plan	8-K	06/04/10	10.3	
<b>Material contracts—Leases</b>					
10.29	Lease, dated September 16, 2010, between Curis, Inc. and the Trustees of Lexington Office Realty Trust relating to the premises at 4 Maguire Road, Lexington, Massachusetts	8-K	9/21/10	10.1	
<b>Material contracts—License and Collaboration Agreements</b>					
†10.30	Collaborative Research, Development and License Agreement, dated June 11, 2003, between Curis and Genentech, Inc.	8-K	07/10/03	10.1	
10.31	License Agreement, dated August 5, 2009, by and between the Company and Debiopharm S.A	10-Q	10/29/09	10.1	
<b>Material contracts—Miscellaneous</b>					
10.32	Registration Rights Agreement, dated June 13, 2003, between Curis and Genentech, Inc.	8-K	07/10/03	10.3	
10.33	Common Stock Purchase Agreement, dated June 11, 2003, between Curis and Genentech, Inc.	8-K	07/10/03	10.2	
10.34	Placement Agent Agreement, dated January 22, 2010, by and among the Company, RBC Capital Markets Corporation and Rodman & Renshaw, LLC	8-K	1/22/10	1.1	
10.35	Form of Subscription Agreement, dated as of January 22, 2010, by and among the Company and the investors named therein	8-K	1/22/2010	10.1	
10.36	Form of Warrant, dated January 22, 2010, issued pursuant to the Subscription Agreement, dated as of January 22, 2010	8-K	1/22/2010	4.1	

<u>Exhibit No.</u>	<u>Description</u>	<u>Incorporated by Reference</u>			
		<u>Form</u>	<u>SEC Filing Date</u>	<u>Exhibit Number</u>	<u>Filed with this 10-K</u>
10.37	At Market Issuance Sales Agreement, dated June 13, 2011, by and between the Company and McNicoll, Lewis & Vlax, LLC	8-K	06/13/11	1.1	
	<b><i>Code of Conduct</i></b>				
14	Code of Business Conduct and Ethics	10-K	03/08/11	14	
	<b><i>Additional Exhibits</i></b>				
21	Subsidiaries of Curis				X
23.1	Consent of PricewaterhouseCoopers LLP				X
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act/15d-14(a) of the Exchange Act				X
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act/15d-14(a) of the Exchange Act				X
32.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(b)/15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350				X
32.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(b)/15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350				X
+101.INS	XBRL Instance Document				
+101.SCH	XBRL Taxonomy Extension Schema Document				
+101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
+101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
+101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
+101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

# Indicates management contract or compensatory plan or arrangement.

† Confidential treatment has been requested as to certain portions, which portions have been separately filed with the Securities and Exchange Commission.

+ Furnished, not filed, herewith.

## SHAREHOLDER INFORMATION

Curis, Inc. and Subsidiaries

### OFFICERS

*Daniel R. Passeri*

President and Chief Executive Officer

*Michael P. Gray*

Chief Operating Officer, Chief Financial Officer, Treasurer and Secretary

*Maurizio Voi, M.D.*

Chief Medical and Chief Development Officer

*Mark W. Noel*

Vice President, Technology Management and Intellectual Property

### MARKET INFORMATION

Our common stock has traded on the NASDAQ Global Market since August 1, 2000. Our trading symbol is "CRIS." There were 268 shareholders of record as of February 24, 2012. The following table sets forth, for the fiscal periods indicated, the high and low sales prices per share of our common stock as reported on the NASDAQ Global Market:

<b>FY 2011</b>	<b>HIGH</b>	<b>LOW</b>
1st Quarter .....	\$3.63	\$1.97
2nd Quarter .....	\$4.42	\$3.00
3rd Quarter .....	\$4.30	\$2.70
4th Quarter .....	\$4.72	\$2.87

<b>FY 2010</b>	<b>HIGH</b>	<b>LOW</b>
1st Quarter .....	\$3.70	\$2.05
2nd Quarter .....	\$3.58	\$1.38
3rd Quarter .....	\$1.87	\$1.21
4th Quarter .....	\$2.14	\$1.28

## CORPORATE HEADQUARTERS

Curis, Inc.

4 Maguire Road

Lexington, MA 02421

P: 617.503.6500

F: 617.503.6501

### TRANSFER AGENT

Computershare Shareowner Services

480 Washington Boulevard

Jersey City, New Jersey 07310

P(US): 877-810-2248 (Ex-US)

201-680-6578

TDD: 800-231-5469 (Ex-US)

201-680-6610

[www.bnymellon.com/shareowner/equityaccess](http://www.bnymellon.com/shareowner/equityaccess)

### BOARD OF DIRECTORS

*Susan B. Bayh*

Director, Dyax Corporation, Dendreon Corporation, Emmis Communications, Inc., and Wellpoint, Inc.

*Martyn D. Greenacre*

Chairman of the Board, Life Mist, L.L.C.; Director, Acusphere, Inc., and Neostem, Inc.

*Kenneth I. Kaitin, Ph.D.*

Director of the Tufts Center for the Study of Drug Development; Research Professor at Tufts University School of Medicine

*Robert E. Martell, M.D., Ph.D.*

Director of the Neely Center for Clinical Cancer Research; Associate Professor of Medicine at the Tufts University School of Medicine

*James R. McNab, Jr.*

Chairman and Chief Executive Officer, Palmetto Pharmaceuticals, Inc.

*Daniel R. Passeri*

President and Chief Executive Officer, Curis, Inc.

*Marc Rubin, M.D.*

Executive Chairman, Titan Pharmaceuticals, Inc.

*James R. Tobin*

Retired

Former President and Chief Executive Officer, Boston Scientific Corporation

### INDEPENDENT ACCOUNTANTS

PricewaterhouseCoopers LLP

125 High Street

Boston, MA 02110

P: 617.530.5000

[www.pwcglobal.com](http://www.pwcglobal.com)

### LEGAL COUNSEL

Wilmer Cutler Pickering

Hale and Dorr LLP

60 State Street

Boston, MA 02109

P: 617.526.6000

[www.wilmerhale.com](http://www.wilmerhale.com)

### ANNUAL MEETING

The annual meeting of stockholders will be held at 10:00 a.m. on May 30, 2012, at the offices of Wilmer Cutler Pickering Hale and Dorr LLP 60 State Street, Boston, MA 02109

### SEC FORM 10-K

A copy of our 2011 annual report on Form 10-K, without exhibits, is available without charge upon written request to:

Investor Relations

Curis, Inc.

4 Maguire Road

Lexington, MA 02421

[info@curis.com](mailto:info@curis.com)

## CAUTIONARY NOTE

This Annual Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements about Curis' financial results and expected cash life, the potential effectiveness of its technologies under development and other information pertaining to its various research and development programs, strategies, plans and prospects. Such statements may contain the words "believes", "expects", "anticipates", "plans", "seeks", "estimates" or similar expressions. These forward looking statements are not guarantees of future performance and involve risks and uncertainties that may cause Curis' actual results to be materially different from those indicated by such forward-looking statements. Actual results can be affected by a number of important factors including, among other things: adverse results in Curis' and its strategic collaborators' product development programs; difficulties or delays in obtaining or maintaining required regulatory approvals; Curis' ability to obtain or maintain required patent and other proprietary intellectual property protection; changes in or Curis' inability to execute its business strategy; the risk that Curis does not obtain required additional funding; unplanned cash requirements; risks relating to Curis' ability to enter into and maintain important strategic collaborations, including its ability to maintain its current Hedgehog pathway inhibitor collaboration agreement with Genentech; competitive risks; and other risk factors described under the caption "Risk Factors" in the accompanying Annual Report on Form 10-K and any subsequent reports filed by Curis with the Securities and Exchange Commission. In addition, any forward-looking statements represent Curis' views only as of the date of this Annual Report and should not be relied upon as representing its views as of any subsequent date. Curis disclaims any intention or obligation to update any of the forward-looking statements, whether as a result of new information, future events or otherwise.



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